BEFORE THE

UNITED STATES DEPARTMENT OF DEFENSE

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In the Matter of: :

ARMED FORCES EPIDEMIOLOGICAL :

BOARD :

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The Armed Forces Epidemiological Board met, pursuant to notice, DR. LEWIS KULLER, President, presiding, at 6058 Aspen Avenue, Hill Air Force Base, Building 1295, Ogden, Utah, 84056, in Poe Conference Center, on Thursday, February 23, 1995 at 8:10 a.m.

ATTENDEES:

DR. LEWIS KULLER, President

COL. L. PITT TOMLINSON, USA, MC
Acting Executive Secretary

DR. JAMES R. ALLEN, M.D., PH.D.
DR. MICHAEL S. ASCHER, M.D.
LT. CDR. DAVID ARDAY
DR. JOHN BAGBY
COL. WILLIAM H. BANCROFT
DR. CLAIRE BROOME
CDR. GORDON CLIFFORD, CFMS, CDLS(W)
MAJ. GEN. STEPHEN CONDON
MR. JESS EDWARDS
DR. GERALD FLETCHER
LT. COL. SHARON FALKENHEIMER

DR. JACK GWALTNEY
DR. BARBARA C. HANSEN, PH.D.

ATTENDEES: (Cont'd)

SSGT. JOHN HARRISON
MS. MARCY HESS
DR. DAVID KRAUSE
COL. ROBERT LEITCH, RAMC
DR. RUSSELL V. LUEPKER, M.D.
DR. DAVID NALIN
COL. FRANCIS O'DONNELL
DR. DENNIS M. PERROTTA, PH.D.
DR. GREGORY POLAND
LT. COL. MIKE PARKINSON
MAJ. SCOTT STANEK
DR. CLADD E. STEVENS, M.D.
CAPT. DAVID H. TRUMP, MC, USN
DR. MARTIN S. WOLFE, M.D.S.

STAFF:

MS. JEAN WARD

AUDIENCE QUESTIONS:

LT. COL. BRUCE JONES
MAJ. ROCHELLE DUCHARME
LT. COL. PATRICK KELLEY
MR. DON FLETCHER

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P R O C E E D I N G S

(Time noted: 8:10 a.m.)

DR. KULLER: I think we'll get started. I think the microphones are off.

THE REPORTER: They are not amplifying.

DR. KULLER: What?

THE REPORTER: They are just for recording.

DR. KULLER: They're just recording, not amplifying. So if you can't hear, that's the breaks.

I'd like to welcome everybody to the Armed Forces Epidemiology Board Meeting, and obviously this is a beautiful conference facility and we appreciate the hospitality of Hill Air Force Base, especially Colonel Falkenheimer, for inviting us here.

It's nice to see in person the facilities and what the issues are in relationship to the health concerns first hand, and we'll have a nice

visit today to the Air Force Base.

Just a couple of very brief announcements. Colonel Peterson has retired from the military and has taken a position at the Armed Forces Institute of Pathology, the AFIP. I always call it AFIP. I never know what it means. But it's the Armed Forces Institute of Pathology at Walter Reed, and so he has left and sent his regards.

Colonel Tomlinson has agreed to step in today and help us along through the agenda and answer any of our pressing questions, and he'll give us a few words in a moment.

I think that we have an interesting agenda, and especially, as you know, talking about the issue today and later on in the day, telemedicine and hepatitis A.

I think there are a few other issues that we'll try to cover today which have surfaced that relate to some of the other things that we've talked about in previous meetings, and I'll try to bring up some of the previous meeting activities.

Yesterday there was a meeting of the group that deals with injuries and we'll have a report on that. I'm delighted to see that that whole program

seems to be taking off, and that was an important accomplishment, I think, of the Board and of others in trying to develop that whole program. I'm really very pleased that we seem to have gotten that really off the ground.

Colonel Tomlinson?

COL. TOMLINSON: Yes. Dr. Kuller, and members of the Board and guests. Colonel Peterson, he's retiring. And, as Dr. Kuller said, has accepted a position at AFIP. He had originally asked Colonel Erdtmann to serve in this place for this meeting and then Colonel Erdtmann's plans changed. So he asked me to, so I will be serving in Mike's stead. I think one of my jobs is to try to keep things on time and to keep people rounded up and getting into their seats.

So, I think we will have to make a special effort to get through the agenda on time over the next day and a half.

Colonel Peterson has notified Health Affairs of his retirement and that a replacement would be necessary. The usual mechanism is that each of the Surgeons General nominates an individual from that service for the position of Executive

Secretary.

I don't know where that process stands right now, but over the past three weeks I've had an opportunity to work with Jean Ward. And Mike left on the 1st of February, so Jean has really attended to all of the details, the planning and the coordinating of this meeting from her office.

And here at Hill Air Force Base, Colonel Falkenheimer and Staff Sergeant Harrison have worked long and hard and have attended to all of the details here and arranged for us to have this very nice meeting room.

So, I want to thank Jean Ward and Sharon Falkenheimer and Sergeant Harrison in advance for all the work they've done up until this point. And I know they have a lot more to do the next couple of days.

I want to remind everyone that the proceedings are all recorded and then transcribed. And these microphones are set throughout the room. When there are questions or comments, if the individual speaking would come forward and speak into a microphone and identify himself by name and organization or service.

If there are any problems over the next day and a half, if you could come to me or Jean Ward, we hope we'll be able to help you. If not, we'll turn to Colonel Falkenheimer and Sergeant Harrison.

I will now turn this over to Colonel Sharon Falkenheimer who will give us a little bit more information about the meeting today.

LT. COL. FALKENHEIMER: Good morning. On behalf of Major General Stephen P. Condon, Commander of the Ogden Air Logistics Center, which is located here at Hill Air Force Base, I'd like to extend a warm welcome to the base and to Utah. And as Colonel Tomlinson said, please be sure to let us know if there's anything that you need that hasn't been taken care of.

Also, Dr. George P. Taylor, who's the Medical Group Commander here, unfortunately has to be away this week, but wanted to send his greetings to you.

I don't know if you had a chance to read the welcome packets at all, but just to give you a little bit of background, Hill Air Force Base and Ogden Air Logistics Center are one of five Air Force Air Logistics Centers where what's called Program

Depot Maintenance or the complete overhaul of various military primarily Air Force systems takes place. And you'll get an opportunity to get a little introduction to that later in the morning. We won't be able to show you everything but we did select some areas that are representative of different industrial processes and health concerns.

We also have a very active flying mission which is not true of all the Air Logistics Centers. We have a Test Squadron. After the aircraft go through a complete overhaul, have been taken apart and put back together, painted, they have to be flown by test pilots to be sure that everything had been done correctly before they go back to the field. And we also have an entire wing of F-16's here that belong to Air Combat Command, so you may see them flying.

Another major responsibility of the base are the large training ranges for various air to ground and air to air type flying that are to the west of the Great Salt Lake.

General Condon is going to come and welcome you at 9:15. He had an earlier commitment. And for the military in the room, you don't need to stand

when he enters the room. And he'll just be here briefly.

I'd like to also welcome our Canadian colleague and people from other departments, like Commander Ungs from the Coast Guard, as well.

I'm going to turn the meeting over for a few minutes to Staff Sergeant John Harrison, who's really done most of the hard work to prepare the conference and he's going to give you some administrative announcements. Then I'll briefly introduce our next speaker who will tell you about our Occupational Health and Environmental Hazard Tracking System at the base, and then we'll have General Condon's visit.

And now, Staff Sergeant John Harrison, who is in our Health Promotion, Health and Wellness Center Office, who will just give you a few administrative announcements.

SSGT. HARRISON: Good morning, ladies and gentlemen, and welcome to Hill Air Force Base.

My name is Staff Sergeant Harrison. I'm the NCOIC of the Health and Wellness Center and I'd like to say I hope all of your accommodations were adequate and that you've enjoyed your stay thus far.

I hope those individuals who attended the social last night for the AFEB Board enjoyed themselves.

We have five phones for your availability. They are located out the door and to your left. And then back to your left there are cards in each of those stations that give you instructions on how you use the phones. The first line is a commercial line. All the lines are Autobahn.

The bathrooms are located toward the exit. The ladies' room is to the left and the gentlemen's room is to the right.

If we do have a fire alarm, ladies and gentlemen, we need to exit the building through the front doors. We need to cross the first street and go next to the road. It's the perimeter road.

And we also have the coffee and the beverage again this morning for you, for the next day and a half. If you haven't paid for that -- so far, I know some of you have. If you'll just see Mrs. Ward, she'll collect the money on that.

And that's all I have to say. I hope you have a nice day and enjoy your stay here at Hill Air Force Base.

LT. COL. FALKENHEIMER: Now, Ms. Marcy Hess will give a briefing on what we call Phoenix, which is our Occupational Medicine and Bio-environmental Engineering Public Health Tracking System. And then an introduction to a further refinement of that system called Command Core.

Mrs. Hess has been at Hill for about 18 years. She's very experienced in computers. She's been a software developer in the past and she was here when the PHOENIX System began in January of 1987, so she really got in on the ground floor.

She's currently the Technical Director of both PHOENIX and Command Core, and our Branch Chief for Computer Resources within my squadron. And she also supervisors about six systems personnel.

So, I'll turn it over now to Marcy Hess.

MS. HESS: Good morning. I'm Marcy Hess. Here at Hill Air Force Base we're running an occupational health surveillance system called PHOENIX. In the early '70s to mid-'70s they had a cancer scare in Building 100. And that's when it was determined that we needed to actually do an automation of the medical data and the data that we're tracking on our workers.

At that time they decided to do a prototype on a system called COHESS. In COHESS, they started collecting all of the medical data for workers on the base for mainly the civilian workers. And then with PHOENIX, we went ahead and started tracking on military and civilian workers on Hill Air Force Base.

PHOENIX stands for promoting healthy occupational environment through information exchange. The objective is the surveillance of hazardous material use and health status of the workers in relation to the work environment.

We have a work triad; the work process, the workers and the workplace.

We actually are grouping the workers into potential exposure groups. When bio-environmental engineering goes out into the work area, they actually are grouping the workers into groups, and they do this based no chemical exposure equal to or exceeding the action level; materials that contain a known or suspected carcinogen; hazards above the standard without personal protection equipment; job functions known to be potentially harmful; directed occupational physicals; materials that require a

license; exposure times that exceed policy; and physical hazards.

We are interfacing with the standard personnel systems to gather the data on our workforce, and we're planning on maintaining the workers for at least 50 years. A lot of it will be their entire work career while on base and then collecting and maintaining the data after they retire. We're collecting the Social Security number -- these are just a few of the elements that we track from the personnel systems -- the name and birth date; the job code; organization; and potential exposure groups that they've traveled to while employed on the base; sex/race; job status.

We have a database for the occupational medicine and we're tracking all the occupational physicals that the employees receive while employed. Any clinic visits for exposures, hydrosene exposures, any type of exposures; any known cancers. We also are tracking all of the lab results and also the lab normals so that we can do comparisons. The doctors' diagnosis, the medical health questionnaire and the death certificate data.

We also have hearing conservation that

we're tracking where we track all the audiograms that they receive and we are interfacing with a HEARS Program. We are tracking all of the employee health training and the accident/illness tracking.

We also have another database, the industrial hygiene area, where we're tracking the employees' work assignments, equipment that generates or controls hazards; hazards physical, chemical, biological. We also are showing all the controls that are required for the potential exposure group; engineering, personal protection equipment and admin.

The sample results, area samples and personal samples; the materials, the chemicals that are contained within the materials and the percent of the chemicals; and also the potential exposure group, all of the information about that group.

Benefits of the system. We're able to comply to EPA and OSHA. We are reducing compensation costs. Trending, we're doing the medical trending, the audiogram trending, illness/injury trending. We are producing a lot of management reports: the EPA/OSHA target changes -- when they change standards we're able to track the

workers that are being affected by the change in standards; pollution prevention; hazardous material; personal protection equipment; and the occupational physicals and the elements that make up those physicals.

We also have two additional charts in your packages that we don't have on the screen and that's just showing that we are currently in the process of re-coding the entire PHOENIX into the Command Core system.

In doing this, we're doing a lot more tracking for the waste disposal. We also are doing pollution prevention tracking with the system, and then we also have all the current modules within the PHOENIX. They're being rewritten into another relational database module on Oracle.

We also have the screen, the main menu. And the main menu, you're going to see the existing main menus from the PHOENIX system and in addition, the pollution prevention, the material management that we're currently doing now but we'll be doing it in greater detail, and then we also have the waste management that will be part of the Command Core.

Any questions?

DR. KULLER: Does the system improve any individual monitoring that is listed? Do you monitor the workers? Do you collect bloods? Do you collect the pulmonary function?

MS. HESS: We do.

DR. KULLER: Do you collect cells to look at changes, genetic changes, things of that sort?

MS. HESS: WE are doing like the pulmonary functions. We're doing CBC's, Chem-1's, all of the occupational health requirements of the occupational physicals. We also are collecting sampling; air sampling, noise dosimetry sampling, any personal sampling that was conducted on the employee in his work area.

DR. BAGBY: I have two questions. One, how long has the tracking system been in effect? And if it's been in effect long enough, what degree of success are you having in following those who have left here that you plan to cover for 50 years?

MS. HESS: We actually have been running PHOENIX since January of 1987. We had COHESS up and running for about eight years. We did take all of the data that was collected -- most of it medical and the work assignments and demographic

information, and we did load all of that into the new PHOENIX computer system.

So, in some areas, in different areas of the medical module, we do have up to 20 years of data. We're keeping all the data on line so that if we have a comp claim or anything that's filed after the employee does retire, we can pull up the information, actually show where he was assigned, what chemicals he was exposed to, any personal sampling that was conducted on that employee.

DR. BAGBY: Are you doing any routine follow-up of the people who have retired?

MS. HESS: We are not, of the people that have retired. We are doing routine trending of the current workforce.

LT. CDR. ARDAY: Could you tell me a little about how the potential exposure groups are defined and determined?

MS. HESS: Bio-environmental engineering has a requirement in hazardous areas, potential hazardous, to go in and do annual surveys, at least an annual survey on the hazardous areas. When they do this, they go into a building or a shop and the break it up based upon workers' exposure.

If they go into a welding area and they find other functions other than welding and maybe some administrative area, they would break the administrative area up into a group, those that do the welding into another group, and then the additional grouping based upon the potential exposure that they find in the shop.

LT. CDR. ARDAY: So an individual is linked to a PEG or a group or a number of PEGs throughout his career?

MS. HESS: You bet. And we actually track when he goes into the new one and when he leaves. If he's required to have a physical or not, an audiogram or anything like that, we are doing all of the scheduling and generation of who's required to have a physical and when they come in. And we are also doing block month scheduling of these employees.

LT. CDR. ARDAY: I guess the last question then would be the PEG's are based on individual chemicals or job functions or a combination or both?

MS. HESS: It can be a combination of both. A lot of it is just the professional call of the industrial hygienist.

DR. BROOME: Could you tell us if your analysis of the data has resulted in any sort of changes, for example, with the hearing conservation module or the injury tracking?

MS. HESS: With the hearing conservation, now that we are tracking PHOENIX, what we're doing is after we do audiograms on a potential exposure group, we'll do trending. And if they see a high rate/percentage of temporary shifts, they'll go in and do additional training to reduce those. And we have seen a reduction in permanent threshold shifts by doing this.

DR. BROOME: And with injuries?

MS. HESS: The injuries and illness we've been doing. It's a relatively new module. We've been doing it probably since '89. And they are able to go in and target some areas for like carpal tunnel syndrome or repetitive trauma and go in and do additional education to try to prevent and maybe even go in and do some readjustments, some administrative controls to reduce injury.

DR. KULLER: Is the system unique to the base here or is it a -- I'm talking about the database system -- or is it something that's used

across the Air Force or is it used -- is it linked to NIOSH in some ways or is it linked to some other systems?

MS. HESS: We actually are running it at all the Air Logistics Centers and Wright Patterson Air Force Base. So, a total of six bases, the big logistics maintenance centers.

We also do have the NIOSH data that contains all of the information about the chemical.

DR. KULLER: And how about the systems that NIOSH uses? In other words, this is a very nice tracking system. Do you tell NIOSH about it or other people about it so that they may not have to rediscover the wheel or something?

MS. HESS: NIOSH has been out. There's been a lot of different companies that have looked at this system. In fact, Proctor and Gamble was running this same system worldwide. And they're in the process of doing the same thing that we're doing. They actually are rewriting it into an Oracle database.

DR. KULLER: Has this been published anywhere? I mean, the description of the system and how it's used?

MS. HESS: I don't think so. I know the Surgeon General's Office has done a lot of promoting of it in the early '87s, '88 and '89.

LT. COL. FALKENHEIMER: A couple of things I think that go to your question. The current developer of Command Core, BDM Corporation, I think does plan to market this.

MS. HESS: They do.

LT. COL. FALKENHEIMER: It's a combined civil/government effort and -- pardon me?

DR. KULLER: What does that mean?

LT. COL. FALKENHEIMER: The future system which incorporates PHOENIX and then adds in the hazardous waste tracking and makes it really a comprehensive environmental/occupational system is being developed under contract to our Command by a company called BDM International. I think it's BDM International. And it's sort of under the Gore re-engineering idea of civil/military cooperation, and they're planning to market it in the civil sector as well.

The other thing is we had a meeting here a week or two ago with representatives not only from the Command but from the Air staff and they're

looking at various occupational medicine tracking systems with the idea, I think, of selecting one to be used Air Force wide, but that decision hasn't been made yet.

This is a relational database, though, which is not true of some of the others that are in use. Some of the others are pretty limited and they're structured into forms rather than data you can interrelate independently.

Paul?

DR. POLAND: A couple of questions for my understanding of the database. Somebody would get entered into this database when they first enter work on one of the six bases that you've identified?

MS. HESS: Correct.

DR. POLAND: What percent of those personnel will spend their career at one of those six bases?

MS. HESS: We haven't done studies like that. We actually have looked at -- if it's a civilian worker, they will actually spend almost their entire career at one location, normally about 30 years. If it actually is military, they do actually transfer a lot and they could go anywhere

within the Air Force, not necessarily stay within the logistics.

But there is one other system that is being run Air Force wide at the other bases that tracks a lot of the information that we're tracking, so they do have some data collection going on

LT. COL. FALKENHEIMER: Another thing sort of on that subject. You may not know that most of the Air Logistics Center personnel are civilians at this base. For example, there are about 13,000 Civil Service employees and around 4,500 military.

So within our Command, the bulk of the depot workers are basically in our logistics centers for their career.

DR. POLAND: So when you collect, for example, doctors' diagnoses, you collect that information even if they're seen at a non-military facility, if they get care outside of the base?

MS. HESS: What we're doing right now for the occupational physicals, all of that data is -- actually all the physicals are done on base in the clinic that we work at. If they go outside for referrals, the data that we collect would only be if it's related to an occupational exposure, cancers,

or if it's occupational related. Then we do collect and enter that data.

DR. POLAND: And one last question. Has there been any reason or thought to collecting data on the dependents of female personnel?

MS. HESS: We haven't addressed that at this point, no.

DR. ALLEN: One of the facts of a system like this is that you cumulate far more data than most people have a chance to look at. Do you have access to some environmental and occupational medicine people, epidemiologists who have the luxury of just asking questions and doing some analyses on some data that may not be obvious from the routine analyses, the trending and that sort of thing?

MS. HESS: We have had quite a few calls about the data because word is getting out that we are collecting a lot of data. We've had quite a few calls from Brooks on looking at JPA, compared to the JP-4 and if it's causing liver function abnormalities increase.

So we have had quite a few calls but we're expecting quite a few more now that we have more data.

LT. COL. FALKENHEIMER: Another area has been new standards. We've done some analysis for the Air staff on what would be the impact of changing some standards on the chromate paint, various chromate levels and on cadmium.

Another area -- you've kind of hit on one of our real problems, as most of us are very busy in our day-to-day effort. One thing I've been looking into recently is talking with Dr. Zelnick who does the occupational medicine training of our aerospace medicine residents down at Kelly, and also the head of the Aerospace Year down at Brooks, to try to tape some of the residents who need to do projects. And their problems is they don't have time to collect data, so they need a ready-made source.

The Air staff is more aware of it now and we'll probably use it more. And we do need, I think, to make a closer link with what's called OPHSA, the Office of Prevention and Health Services Assessment at Brooks, which is our new Air Force health studies agency, I guess you might say.

Dr. Peterson will probably talk in more detail about that. But they have not to date been involved.

But part of the idea of briefing it here, too, is if you have any occupational health questions that come to the Board, to make you aware that there is this system and we may be able to answer a query on even very specific types of questions over a several year period.

Dr. Ascher?

DR. ASCHER: We face that problem in the cohort, as Jim mentioned. We wrote a public tape of some very selected variables that were de-linked from any identifiers and it was widely distributed. I'm wondering if you're thinking of making public any of the sort of the raw data for people in the cohort as Jim suggests?

LT. COL. FALKENHEIMER: I don't think there's been -- to my knowledge there hasn't been any discussion in either direction, pro or con. I don't think the issue has really come up to date.

DR. ASCHER: You might think about it.

DR. BROOME: Just a clarification. The medical outcomes data that you have, is it just on the occupational health exams and occupationally related follow-up, or do you have a computerized database of general medical care for at least

military and any civilians?

MS. HESS: Mainly occupational. Very little of the other type of data.

LT. COL. FALKENHEIMER: There is a system, though, being tested at several bases and we may soon become a site to actually track all out-patient visits by code for what the problem was. That's one thing that's been a weakness in our system. We have all kinds of in-patient data, but our out-patient data has been limited. And there is a system like that at limited bases right now being tested.

DR. KULLER: I think one thing that you could do that might be interesting is to look at some of the new individual -- what I would say personal markers of exposure. There's a great deal of interest in the occupational area right now in the environmental toxicology moving much like in infectious diseases where they basically can look at an individual and look for subtle changes related to certain kinds of somatic mutations that will appear in relationship to exposure. They would have no health effects which would be overtly obvious but will tell you whether an individual has been exposed even in the short-term with -- caught

people with DNA adapts and things of this sort. The big advantage that you have in your system is that you have both an excellent data management system and an excellent occupational exposure system and the real interest in this field, I think, is really whether you can find ways of monitoring recent environmental exposures where the actual individual environmental exposure obviously is difficult to determine.

We do it with noise, obviously, where we can measure hearing thresholds and you're doing that very nicely with measuring changes in hearing thresholds. And especially out in the environment where there are probably many, many environmental carcinogens, but probably the exposures are fairly low to any group of individuals and the risk of a carcinogen is probably related to being unlucky in terms of how much you get exposure and how much genetic susceptibility you have.

So that the real -- I think a lot of emphasis now is moving into looking at individual sort of subtle toxicology and it might be worthwhile to let people who are interested in this area know about this database. This is my question of whether

the epidemiologists are digging into the database.

The environmental toxicologists who have gotten really quite interested and haven't come up with anything yet, by the way, that solves the problem. That's why it's interesting. They're looking for something. May turn out nothing works. But at least it might provide the opportunity on your annual exams to look at -- some of these are fairly inexpensive, so that it can be done as broad screening, much like you would screen people for exposure to some infectious agent.

LT. COL. FALKENHEIMER: I think something like that would really have to be set up as a research project maybe under the Human Systems Center, which could be carried out here. We do have some cooperative research. We have the University of Wisconsin doing a project on sperm analysis in fuels workers, for example. There are some specifically targeted studies going but there are a lot more that could be done if researchers are interested.

But we wouldn't have funding to do a research sort of protocol here unless it were approved by one of the research centers.

DR. KULLER: I agree. Yes. I was thinking that people -- because this would become rather important. It's going to become important in the future in terms of monitoring these populations when you're doing annual -- you know, changing the annual traditional occupational physical examination to begin to focus down at the biological molecular level for what really is rather superficial right now in terms of actually identifying true exposures.

LT. COL. FALKENHEIMER: And if we had more exact markers, we could probably save a lot of money on a lot of nonspecific exams that we do.

DR. KULLER: That's right.

LT. COL. JONES: How many workers monitored by your system? I missed that.

MS. HESS: We actually have the capability of monitoring the entire workforce, which right now is probably real close to 14,000 workers.

LT. COL. FALKENHEIMER: Just at this base.

MS. HESS: At this base. Then we do have the system running at the other logistics centers and Wright Patterson.

LT. COL. FALKENHEIMER: So in the range of 50,000, I would say, or more.

MS. HESS: Yes. We also have the history on the workers that have left. So the workers that we're actually tracking would be a lot larger.

LT. COL. FALKENHEIMER: Dr. Fletcher?

DR. FLETCHER: Back to -- Sergeant Harrison mentioned the Health Wellness Center. Is this doing anything sort of in line with what Dr. Parkinson has done in other parts of the Air Force? Is this a very large program both for the civilians and the military personnel?

LT. COL. FALKENHEIMER: It is open to everyone. At the moment, the Health and Wellness Center isn't open. It's opening next month. We have had, though, a health promotion flight which Major Ducharme in the audience is the director of, and they for a long time have been carrying out various prevention programs, such as stress management, smoking cessation, nutrition counseling. They do health risk assessments.

We encourage the units on the base to do them as a unit for the Commander to call the health promotions flight and ask them to come out. And they give a questionnaire on basic preventative medicine sort of questions and then have individual

meetings with the individuals where they draw blood for cholesterol screening and also do blood pressure monitoring.

And then once all the data is back, they individually meet with the people and counsel them on the risk behaviors and what can be done and refer them to any of the other available resources on the base, some of which are not with our squadron. Like Family Advocacy has a large number of programs that can support various family situations and that sort of thing.

So that's been a fairly active program. It's going to get much more active when the Health and Wellness Center opens. They'll take over the cycle ergometry program for the base. And one of the problems with that program has been that each unit has its own people with multiple testers, so the uniformity -- it's hard to ensure that testing is uniform from squadron to squadron or group to group.

And the people who will be under contract will be both a Ph.D. physiologist to look at people who aren't passing and give them individualized instruction on how to get in shape and meet the

criteria, and there'll also be fitness experts who will oversee all of the testing and be sure it's done uniformly around the base. So that will really add to that aspect. And we'll also have quite a few additional personnel then and be able to free up Major Ducharme to do a lot more in the health risk assessment area.

DR. FLETCHER: Will you be able to get into the civilians as well as the military personnel?

LT. COL. FALKENHEIMER: Actually, to date they've been the primary users.

DR. FLETCHER: Oh, really?

LT. COL. FALKENHEIMER: Either family members or Civil Service workers. The military has not voluntarily in large numbers come in for these types of things. And even -- I don't know. You may be able to give a percent of squadrons that usually show up for the health risk assessments. They're voluntary, so what percent? Maybe 20 or 30 percent, you think?

MAJ. DUCHARME: Well, right now it's still kind of in the bottom, ground floor for this, but we're trying to --

THE REPORTER: Come to the microphone.

MAJ. DUCHARME: Oh, all right.

LT. COL. FALKENHEIMER: I mean, when you go to a squadron, though, what percent will normally come?

MAJ. DUCHARME: Oh, actually a lot of it. It depends on the actual squadron, but a lot of them right now that we're targeting is just the military. But we're offering it to civilians also.

LT. COL. FALKENHEIMER: I meant the educational programs are primarily used up by the civilians, right? And the family members?

MAJ. DUCHARME: Yes.

LT. COL. FALKENHEIMER: Dr. Ascher?

DR. ASCHER: I'm wondering how you respond to a real life problem like respiratory disease or a sick building syndrome or something.

LT. COL. FALKENHEIMER: Well, actually, that's a good question because --

DR. ASCHER: If you're not linked to the civilian care, that can make things very difficult, and I wondered how you would respond to those examples.

LT. COL. FALKENHEIMER: Well, actually, we're in the midst of investigation of concerns

about cancers in one area of the base and Dr. Grayson is actually helping us with that, too. He's here from Brooks. But what we've done is -- originally workers listed a fair number of people in several buildings that had died of cancer over the last -- or the original story was it was like 40 people over five or 10 years. Eventually, it was more like 20 people over 15 years or something like that.

But basically, what we did was immediately Bio-environmental Engineering and Public Health went out to the building. We've got a lot of sampling on those buildings. The only real health threat there is asbestos and it's primarily in the roofs and in the attics in ways that it's not easily aerosolized.

We have recently found some in one area of the ceiling tile, but basically we go out and look at the bio-environmental engineering side, do some additional sampling.

We also met with the management and the people concerned to gather data. Several people you'll be meeting later who will be on the team to guide you around have been involved in this doing the legwork, but Public Health and I met with

management and the people concerned early on to try to get a comprehensive list of who the people were, what cancers they had, and also explain our game plan.

Then we have an oncologist here who is a former reservist and he's been looking into the death certificate data in Utah for the people who were identified, as well as the frequencies of various cancers and they've turned out to be pretty typical so far of Utah in general.

We also had a meeting with all the individuals who wanted to come from those buildings to explain what we were doing, to have the oncologists explain how cancer is caused and what would be expected if it were a point source exposure versus this mixture of prostate cancer, lung cancer, all the standard cancers you see.

As far as the civilian health system, if we were having an actual outbreak, we can always as the individuals to provide that data. I don't think we can require it, though, if they're seen by their private physicians and it's not an occupationally related injury for which they are seeking a claim or that sort of thing.

But basically, mobilize our team, which includes Public Health, Flight Medicine and Bio-environmental Engineering to go out and look at all aspects and then try to do basic epidemiology looking at comparisons with the frequency in the local area and that sort of thing.

I don't know if that's quite what you're asking but since they're not in the military.

DR. ASCHER: I'm just wondering how successful you are.

LT. COL. FALKENHEIMER: We don't have as much control over them and looking into their health records, if it doesn't concern their employment. Where, with the military individual, we can look at all of their records all of the time.

DR. ASCHER: I'm just wondering how successful the package is when you're done and does it resolve the concerns. Does it close the issue?

LT. COL. FALKENHEIMER: Well, I think most of the times it's like most investigations. Some people didn't think there was a problem to start, a small number. There's a small number that are never satisfied no matter how much data is gathered. And there's a time at which you have to cut off sampling

and just say, you know, we have reasonable confidence that there's nothing going on.

Most of the people, like at the public meeting we had, I think were reasonable. They were concerned. They had questions. But once they had the facts and information about what was going on, they seemed to be reasonably reassured.

DR. ALLEN: Do you collect any serum specimens and store them for potential future studies?

LT. COL. FALKENHEIMER: I don't think so. Not that I'm aware of.

MS. HESS: No.

LT. COL. FALKENHEIMER: Although we do -- one thing we do have is all of the military are having samples drawn actually for DNA identification. If they're killed their remains need to be identified in the future and those are started at the Armed Forces Institute of Pathology, as well as there's a small sample in their medical record. But those would be taken at various times and wouldn't really be linked to any specific exposure.

COL. O'DONNELL: I want to ask a couple of

questions about the relationship between this system and others. You mentioned pollution prevention and hazardous materials. I assume that the base has other information systems which are full-time dedicated to environmental programs. So what's the relationship between your system and those?

MS. HESS: We actually do have a hazardous material tracking system and they're doing all of their material issues to our potential exposure groups, so we know exactly how much of every material is being issued within each of the exposure groups.

We have daily interfaces and also weekly and monthly interfaces with that system. We pass them information on what the bio-environmental engineering group determines to be the required respirators and then they make sure that when they go to -- they only issue them the respirators that they've actually been tested for over in our clinic.

We also pass all the potential exposure or any new potential exposure groups that bio's created, we actually pass them that information daily. We actually are working some future interfaces to track the workers' data, but right now

we're actually doing the quantity issued of the data -- of the materials, actually to the potential exposure groups.

COL. O'DONNELL: So there is a separate information system for the environmental program?

MS. HESS: Correct.

COL. O'DONNELL: Okay.

LT. COL. FALKENHEIMER: But Command Core will command those combine those all in one interactive database.

MS. HESS: It will still be -- yes. It will still be an interface to a hazardous material tracking system, but it will be a more on line interface.

COL. O'DONNELL: Okay. My other questions had -- what's the relationship between this system and the DOD initiative to develop a single occupational health management information system for all the services that's undergoing study by a tri-service group right now?

LT. COL. FALKENHEIMER: This would basically be one of the candidate systems. There are several that are in use in various -- there are at least two in use in the Air Force and I assume

probably more than one in the other services, as well. I don't know.

DR. BAGBY: Several years ago NIOSH designated the University of Utah as one of its national centers of excellence in environmental health/ occupational health. Do you have any contact with them? Are they interested? Have they done any work with their data on that?

LT. COL. FALKENHEIMER: Yes, sir, we do, actually. Dr. Rashmosher who's there is a retired Air Force Colonel and we do have an arrangement. Our occupational medicine services contracted here but the lead physician there has an arrangement with the university for residents in occupational medicine to come out and they often do do some of our trending or other studies while they're here. It's part of their training program.

LT. COL. PARKINSON: Sharon, one of the things that's always a controversy in occupational medicine is the utility of periodic health evaluations. Have you been able to look at your database or have other residents look at it in such a way that you evaluate the utility of routine screening for many of these problems? I sense

there's a tremendous amount of data, a tremendous amount of effort that goes to relatively little health benefit sometimes, based on just my base level experience and hearing the data you collect.

Is there anything that you've done in that area or could do in that area?

LT. COL. FALKENHEIMER: I think we certainly could. To date we haven't but I've been having conversations with our occupational medicine physician about trying to come up with the top 10 or 20 questions we'd like to have looked into which could be tasked out to various residents or if OPHSA wanted to do analysis in that area, we'd certainly, I think, welcome it, welcome the cooperation.

Our biggest problem is we don't have an epidemiologist. I would like to see us get one on staff but to date we don't. I think we could certainly keep one gainfully employed, maybe more than one. Or it could be done -- for instance, OPHSA is in San Antonio and Kelly has our system on line. They could do the analysis without even having to go to any other location.

DR. GWALTNEY: In relation to that question, when I went into preventive medicine in

the '60s, it really was before we knew these things worked, many of these things worked. We thought it was a good idea to control hypertension but we really didn't have the data that was true.

I think what's happened since the '60s is we know a lot of these things really do work. We know smoking cessation works. Control of hypertension, control of serum lipids, seatbelts, certain forms of cancer screening. And so I think we need to adopt the belief that we're practicing things that we know work. Now, they're still limited, but I don't think we need to go back in, in a sense, rediscover the wheel on some of these things. There are new things to come along to be developed and to be evaluated, but I really think health risk assessment and intervention is now a practice, just like therapeutic medicine.

So I think we should think -- and there are plenty of references that have been published supporting this in the Public Health Service. I've forgotten the name of the book, but the little book that has that in there.

So, it's happened gradually and I think it's something that is not -- many people both in

society, general society and in the medical profession, haven't really come around to thinking this is a practice now. We don't have to rediscover the wheel. Let's do those things that we know work and work on the things that we're not sure about.

In relation to participation rates, we've just looked at the program we have at the University of Virginia for 12,000 people, including the Health Medical Center. Our participation is voluntary. It's 30 percent. And the doctors do much worse than the rest of the population. But that's 30 percent of people who wouldn't have had it to begin with, and I think it's going to grow.

LT. COL. FALKENHEIMER: Colonel O'Donnell?

COL. O'DONNELL: Is OSHA represented here? And if so, what do they think of the system?

LT. COL. FALKENHEIMER: They certainly visit here.

MS. HESS: Yes.

LT. COL. FALKENHEIMER: I don't know if they've looked at the system, per se. We had an inspection not too long ago.

MS. HESS: We've had quite a few visits with them on the data we're collecting and they are

quite impressed with the data that we collect on the worker and how we're able to do the personal area -- you know, the area samples, personal samples, and over time collect all of that information on an employee.

They like the database.

LT. COL. FALKENHEIMER: Any other questions?

(No response.)

Thank you. If you'd like to take a short break, we don't expect the General until about 9:15, so if you could please be back in your seats around 10:00 o'clock. Get a little more coffee -- or 9:15. I'm sorry. I misspoke. He should be here about 9:15, so if you could be in at 9:10.

(Whereupon, a recess was taken.)

LT. COL. FALKENHEIMER: Ladies and gentlemen, I'd like to introduce now the Commander of the Ogden Air Logistics Center, Major Stephen P. Condon, who will briefly welcome you to Hill Air Force Base.

MAJ. CONDON: Thank you, Sherri.

Well, it's my pleasure to welcome all of you here to Hill today. I will tell you that we

have already violated one of the rules. I told Colonel Falkenheimer that we were not going to host any conference that I could not pronounce, so -- though we're pleased to make the exception in this case.

As I say, we're really proud to have you here. Pleased that you chose our location as a place to hold your conference.

We're really proud of what we do here at the Air Logistics Center. You'll get a chance to see a little bit of that a little bit later this morning as we show you around to some of our facilities and show you the kind of work that we do here.

We've got, in my estimation, a world class facility in many regards. Some of the things you'll see truly are unique as they exist here at Hill and they don't exist anyplace else. Others, other things that you'll see, are fairly common to the things you will see at any air logistics center in the Air Force.

But as I said, we're really proud of the support that we're providing to our operational customers in the Air Force as well as in other

services. We do a good bit of work for the Navy. Also do some work for the Army and the Coast Guard and other agencies, as well.

If there's anything that we can do while you're here to make your stay more enjoyable or more productive, please don't hesitate to call that to our attention, either Colonel Falkenheimer or any other members of the staff. We're here to serve you. We're here to make your conference as productive as it possibly can be made. And so, as I said, please don't hesitate to call upon us if there's anything that we can do.

I'll get out of your way now and let you get on with your business. Again, we're really pleased to have you here and hope you have a great stay.

Thank you very much.

DR. ASCHER: At the billeting office, somebody said last night, "What are all these skin doctors doing here?"

(Laughter.)

LT. COL. FALKENHEIMER: I'd like to move on and give you a brief introduction to our site visits.

One of the purposes of bringing the Epi Board to Hill Air Force Base was to try to give you a little flavor of what a large military industrial workplace is like in case you get questions on occupational health or preventative medicine related to some of our industrial workers and we're going to show you four sites this morning.

I'd like to now give you a welcome from what we call Team Aerospace, which is really the prevention and aerospace medicine side of the medical group and I'll be introducing some of my staff in a few minutes who will be your tour guides.

The four locations we're going to go to today will give you a good idea of what's called Program Depot Maintenance for Aircraft. That's the complete disassembly, overhaul and reassembly and subsequently flight testing of aircraft, as well as some specialized processes, such as landing gear.

We'll be going to each of the facilities with each of the groups, and each of you has been put into one of three groups. If you look at the back of your agenda, there's a list of each of the three groups and before we leave the room I'll point out to you who your tour escort is, who are the

individuals at the top.

The Board is all in Group A with me and then the other individuals are in the other two groups. So each group will have a military escort, if you have any questions. Some of the locations we may have some of our industrial hygienists or industrial hygiene technicians available to explain and answer questions more on the health side of things. But at each facility there will be a tour guide from the facility who will give you an overview of the industrial processes there.

We do need to give you another badge to wear for the landing gear facility and Staff Sergeant Harrison will give them to you. So during the break between this brief presentation and boarding the buses, please be sure that you get one of those badges from Sergeant Harrison.

The other thing that's really important is that we keep on time because we do have a lot to see in a short time, so if you run out of time in a facility and have a question, feel free to bring it up to us later. We won't be able to make you an expert on each area but what we wanted to do is just give you an idea of the range of things we have

here.

I'll go through in the order of Group A, but you'll basically be seeing all of these, sort of rotating through.

Building 507 on the lower right, just to orient you, the Officer's Club is right in the center where it says "O Club." Most of you have been there and live right near by. Down to the southeast is Building 507 which is landing gear. That's right inside the front gate. That's where depot level overhaul of many types of landing gear systems, everything from small fighters to the C-5 which is our largest cargo aircraft. Can carry about 16 buses, really. Quite a huge landing gear. They do depot level overhaul of all of those types of landing gear.

Some of the processes that occur there, most of which you'll see, are disassembly of the landing gear. That's an area to look for ergonomic concerns because sometimes they have to get into awkward positions. In several of the processes awkward positions can be a problem. They do paint stripping and cleaning of the gear. It goes through a nondestructive inspection to determine what needs

to be done to it and it may need some grinding or additional treatment before it is painted.

They also have a foundry and welding operation to take care of some of the metal problems that are needed. There's heat treatment that occurs to the gear and reassembly, of course.

Some of the hazards there that can occur, you'll see people in various types of protective equipment, everything from complete airline respirators to half-face respirators to just noise protection, but basically there's cadmium and chromates in some of the paints. We've eliminated a lot of the chromate paint but there's still some, particularly in the F-4, which is on its way out. But those are hazards in the paint removal and painting operations.

There's dust from the blasting operations, noise and ergonomic concerns, as I mentioned.

One thing you won't really see is there used to be a large number of vapor degreasers and a lot of potential solvent exposures from chlorinated solvents which have been able to be eliminated by going to parts washers that are basically soap and water operations. So a lot of -- I think if you've

seen other industries, you might think about what you're not seeing there because a lot of the improvements that have been made here have been made to eliminate some of the hazards that were there in the past.

The other three facilities are somewhat related. Building 225, which is in the large upper right area, is the program depot maintenance facility. It's really a large double hangar. And that's where all the F-16's in the Air Force and all the C-130's which is a four engine turbo prop cargo plane undergo depot maintenance, as well as a portion of the Navy's F-18 fighters.

And you'll see what are called docks. They're like individual aircraft stations where the aircraft is placed and worked on at the depot level. And it will give you an idea of the potential exposure groups not being geographic spaces but people that move. So, say, the sheetmetal people would move from aircraft to aircraft to do their job and their zone is wherever they are working. And we have for certain processes mobile exhaust ventilation for when it's needed that can be moved into the area at the time. So you might look for

some of those things.

They do also fuel cell processes where they have to remove liners from fuel cells. There are benzene hazards there. They have to wear respirators for that operation. Sheetmetal and electric, I think I mentioned. And there's also some composite repair that occurs.

There's also, as far as hazards, some cadmium from the sealers that are used, particularly on the F-16's, noise and grinding.

After the depot maintenance facility, another place we'll be going is the Bead Blast Facility which is the little X to the right of 225. It isn't really on the map. But this is a facility that has two large bead blasting booths. You'll see some small bead blasting booths in landing gear, but they can put an entire fighter in the bead blasting booth and strip its paint off by spraying it with high speed beads.

This used to be a liquid process using a lot of solvents and was very messy and also a real environmental problem. And it's a much cleaner process but still hazardous because of the possible exposures to cadmium or chromates in the paints or

other metals. So the people wear airline respirators who are doing that operation.

The first two tours will be about half an hour. These last two will be 15 minutes because they're short.

And then Building 257, which is just south of 225. You'll be seeing the aircraft canopy polisher. I think you probably saw that in your little folder. This is basically an operation where fighter canopies, which are made out of acrylic and polycarbonate get scratched and need to be polished.

This is an operation that used to take over a week by hand and it's accomplished by a robot in approximately 14 hours most of the time. It's not really a very hazardous job, partly because they use a wet process and they have the robot doing it.

They do do some application of sealants and alodine and some small amounts of touch-up painting and drilling, riveting or grinding of metals, but this is one of our -- what's considered a nonhazardous shop.

Any questions on what you'll see? As I mentioned, someone will explain as you go what you're seeing, but wanted to kind of put it in a

framework for you.

We're hoping to show you -- the other major thing Hill Air Force Base does is depot level maintenance of all ballistic missiles and quite a few other munitions, but it's very schedule dependent and this week there's not a lot of operation going on out there, so we didn't think it was worth taking you out. I was out there earlier this week.

So, this will give you a potpourri of industrial processes. I know when I trained in Public Health School and we went out to industry, it was light years different from what I've seen here, the level of containment of things and worker protection is just really leaps and bounds ahead here compared to what I saw in some of those industries in the past.

So if you have any questions, ask the people who are touring you and then if you have any that you think of later, we'll try to answer them for you over the next couple of days.

LT. COL. LEBEGUE: Do we get entered in the PHOENIX for the tour today?

(Laughter.)

LT. COL. FALKENHEIMER: Well, since you won't be there over 30 days this year, I guess we won't have to. Hopefully we won't lose you anyway.

Anything else? Be sure to pick up your badges. Since we need to be at some of the sites by 9:55, please board the buses by 9:45.

Thank you.

(Whereupon, the proceedings were adjourned at 9:30 to conduct the Site Visits, followed by the luncheon recess.)

AFTERNOON SESSION

(Time noted: 1:30 p.m.)

DR. KULLER: I guess we're ready. Anybody have any other comments or anything?

(No response.)

I guess we're ready to start this afternoon, then, right on time.

Colonel Parkinson, do you want to start out?

LT. COL. PARKINSON: Good afternoon, everybody. I bring you greetings from the Air Force Surgeon General's Office. I also want to acknowledge that my predecessor in this dubious position was Colonel Jim Wright. He's here to help. He's now director of the Epi Division in OPHSA, Office of Prevention Health Services Assessment.

What I'd like to talk about today are just two general areas that I find occupying a lot of attention in the Air Force right now. One is the whole area of deployment, support for deployment, deployment arrangements. And the second is the transition of the Air Force Medical Service along with all of DOD into the managed care arena.

That pretty much -- those two activities

probably comprise 99.9 percent of what we do and while there have been diagrams, sometimes they overlap and sometimes they're totally distinct. But they're very similar because we oftentimes ask the same people in the Air Force to do both functions.

Probably the most important development that all of the preventive medicine officers have been working on closely with the ASG for Health Affairs is the generic deployment surveillance plan. Many of you will recall that this had started in advance of the Persian Gulf health experience but certainly the Persian Gulf experience was a major accelerator for this effort.

There has been a 12 point generic deployment surveillance plan, if you will, put together, which talks about the kind of the guiding principles for deployment surveillance. You have to know for pre- during and post-deployment.

The JCS Surgeon's Office, as well as the Army's Surgeon Office, through RARE, both have convened two recent meetings in the past six or eight months that looked at the ongoing problems that the services have in making consistent guidelines and disseminating them to the field and

collecting health surveillance information before, during and after deployments.

This 12 point plan has been basically coordinated through all the major agencies, and I believe they are waiting JCS coordination, with the hope that this would be come essentially -- doctrine may be too strong a word, but it would certainly be the guiding principles, the score sheet, the piece of music that all the services, including the joint commanders would have to play off of so that we all start from the same level and hopefully develop both short- and long-term mechanisms to make sure that we're consistent.

In the Air Force, each one of the services is tasked with collecting epidemiologic information, not just in the general health status sense. As the injury subgroup yesterday indicated, we need it for all types of health conditions but specifically for deployed cohorts.

So the way the system will work is that the Defense Manpower Data Center in Monterey will be providing each of the services with the names, Social Security numbers, demographic information of the deployed cohort so that at some future time we

can do look-backs on whether or not these individuals had a higher incidence of communicable diseases, whether they had a higher injury rate. You pick the outcome but the notion is the first thing we've got to do is identify the exposed cohort, which up until now had not been systematically done.

The place where we're going to do this in the Air Force is at the Epidemiology Division in San Antonio under Colonel Wright, and we're already starting to generate rosters from, for example, the Haiti deployment. We're trying to get information now on Bosnia. And this will become a regular part of the public health preventive medicine effort in the Air Force.

Right now we're restricted in the Air Force to really communicable disease reports which, as you know, is a passive surveillance system. We do not have an automated out-patient medical record. We do have in-patient information. But certainly what we can do is take that deployed cohort three, six, nine months, a year after that deployment and run it against those databases both for communicable diseases and, for example, in-patient, to see if we

see any abnormal patterns in the troops that were deployed.

It's just a first step but to those of us I think in the preventive medicine community a critically important step because we're finally operationalizing some of these things that many of us have known for years we really needed to have a system in place to do.

So that's moving forward very quickly within Health Affairs with all of the services' input.

The other major area involves, of course, managed care and prevention as it relates to managed care. Not only individual clinical preventive services, but health promotion and population based approaches to improving the health of DOD beneficiaries.

Since the time of the last meeting there have been two major meetings, I believe, since this last meeting. There was a tri-service DOD meeting that was hosted by the Office for Prevention Health Services Assessment that looked at the Public Health Service's "Put Prevention Into Practice" campaign, which is a series of clinician, patient and clinic

materials that have been tested, shown to be effective in increasing the utilization of screening counseling and immunization tests.

We basically analyzed those materials; had in the national experts who worked on them. And Dr. Joseph and Dr. McGinnes keynoted that presentation. Dr. McGinnes was then the head of the Office of Disease Prevention and Health Promotion in HHS. And with that, basically kicked off a consensus among the services.

One of the key elements that each of the services in its own way would have to address in order to overcome the barriers and capitalize on the opportunities within each of their respective services to make sure that we optimize the delivery of clinical preventive services under our now new managed care, quote, tri-care health care system.

In order to get the word out, we then presented, asked for from Health Affairs and received about a half hour of time during the Tri-care annual meeting which was held in January before some 750 or 900 hospital commanders and Maj Com leaders and regional medical center personnel, to tell them that this is something that Health Affairs

and DOD are serious about. There are tools out there. We will be disseminating materials through both the Tri-care regions and through the major commander or equivalent structures in the Army and Navy and we will do that within 60 days.

Dr. Trump, myself and Colonel Carroll from the Army, who is the Chief of Family Practice, presented a joint presentation. A theme we're picking up here is jointness. I don't find any issue that I'm working now that's almost exclusively Air Force and that's probably the way it should be. And this certainly is a reflection of it.

One of the problems, though, that this reflects is that Tri-care is a health care system, I would suggest to you, almost, if not in name only, it certainly is an administrative structure. But if you look at the guts of the health care system, do we have in place the infrastructure, the procedures, the policies that an organized managed care system has. And the answer to that is no. We're really learning just how to walk.

And so what we've really got here is clinical practice guidelines. Do we have the clinic organizations that have a way of reporting on

performance for these measures. So, in light of that, the second major aspect of this is the civilian external peer review program. This program has historically looked at in-patient hospital procedures within DOD to see whether or not, for example, our rate of complications with laproscopical cystectomy was the same as in the civilian sector. Are our obstetrical outcomes the same as they are in the civilian sector.

This will be the first major effort that looks at an ambulatory care service. And as such, it represents a major leap forward, I think, in getting to where the bulk of health care is developed, in the out-patient rather than the in-patient setting.

We've had two meetings so far. The co-chair of this is Dr. Shirley Kelley, who's Vice President of JCAHO, which is increasingly getting into the accreditation of managed care plans just like the National Committee on Quality Assurance. And what we are meeting -- we're meeting Monday afternoon to finalize the methodology to obtain baseline information for both the direct and indirect care systems. That is, that that care that

we paid for but don't necessarily deliver ourselves, so that we will have a baseline to start from.

Right now if you asked me what is the level of immunizations among 2-year olds in the Air Force, I don't have a database to look at that. I don't have a database to say what proportion of women over the age of 50 have a mammogram. We've got to not only develop the baseline information so that we can measure our success using "Put Prevention Into Practice" against it, but we've also got to be able to, in the old Peace Corps way, teach people out there how to fish rather than just giving them fish. And we've got to -- we're committed to improving facility self-assessment ability during this process.

So this is very exciting to all of us, I think, because we're linking programmatic implementation to baseline information, ongoing improvement, around something that's going to be measured for health plans. Clinical preventive services make up something like four of the seven quality indicators for health plans. Why? Because there's a lot of consensus they should be done and you can measure them.

One of the aspects of that is basically, right now, as I said, we don't really have, except in name only, a true managed care system. If you pick up an Army or a Navy medical record, the materials on the left side of that chart are all different. The problem list format, the things for immunizations, you know, what types of forms enter out of there.

So one of the notions that we want to do is take the "Put Prevention Into Practice" materials and to standardize a form that would go inside the medical record for all DOD medical records. Now, the key -- this basically is a conglomeration that Major Candace McCall of my office is working on to try to work with the three services to come to some agreement to take before the Board that makes form decisions within DOD as to what should be in the medical record.

But the importance of this is not so much this. This is what our old problem sheet looked like in the Air Force. But it's the notion of a preventive care flow sheet. And it's really -- this single item alone in studies of the "Put Prevention Into Practice" has been shown to increase the

utilization of preventive care. It's not that doctors and clinical nurse practitioners don't want to do prevention. They don't know what needs to be done at what time.

So, getting the clinician, getting the technical people, the administrative help to fill in these flow sheets and make it part of the medical record is one important piece. And right now, we still have forms on the chart that talk about smallpox immunization, which ironically, maybe we'll be talking about again.

But at any rate, we're really outdated. Some of these forms need to be cleaned up, so that we're working on that.

Some of the recent developments at the Office for Prevention and Health Services Assessment. They have numerous projects going on, some 15 or 20, but I just wanted to highlight a couple they were making some rapid progress on.

One is to tap into the CDC Wonder/PC network to avail every one of our bases of CDC's expertise on on line information as it relates to any number of recommendations in public health preventive medicine. We anticipate by the end of

March that all Air Force Bases will have in the Public Health Officer Air Space Medicine Squadron, PC Wonder link-ups such that we will be able to get into that information real time, as well as using Air Force resources of the Epi Division or my office for consultations.

More importantly, though, is the Air Force will become essentially the 51st State on this network. Right now, all of our communicable disease information is transmitted via paper or via message traffic. And what we will be establishing by October is essentially an account with CDC that basically makes all Air Force bases a State with centralized reporting that we then get at the Epidemiology Division in San Antonio. So we'll start getting that type of system that many State health departments now use for disease reporting.

The Health Enrollment and Assessment Review has come to fruition. This, as you may recall, I talked about briefly. But it was a combined health risk assessment tool that also tries to predict utilization for the purposes of enrolling patients in the managed care plan.

The traditional HRA, as you know, looks at

risk factors. But it doesn't look at indicators of potential high utilization that will help you target interventions for that patient or assign them a primary caregiver based on their past history of medical condition.

This product has been largely completed. It has been turned over to Region VI, which is operated out of Wilford Hall Medical Center in San Antonio. And we think that it offers a lot of promise. It will also be used in Air Force Region IV, which is out of Kessler Air Force Base in Mississippi.

Defense Women's Health Research Projects, the Epidemiology Division submitted numerous proposals to look at -- I believe one was out-patient utilization and also Desert Storm experience of Persian Gulf War veterans, to look at their utilization of health services during the war.

Finally, I just wanted to touch very briefly. I know one of the interest items at this meeting was hepatitis B and C recruit policy. This surfaced a couple of years ago, I think, when we were visiting San Antonio at Lackland.

Air Force current policy is, as in all the

services, is that recruit basically donate blood. It says voluntary blood donation. We make it as voluntary as possible, given the whole notion of informed consent in this population is problematic, just as it is in other groups. But nevertheless, we do have the recruits donate blood.

As usual, they're screened but they're going to be positive for any marker of hepatitis B surface antigen or core antibody or hepatitis C antibody, they're subsequently medically evaluated and if they show any signs or symptoms of either acute or chronic hepatitis with specific transanimase elevation, then they are separated, as they can be under existing DOD policy for, quotes, a preexisting condition.

Now, having said that, it raises the question if this is being done de facto in all the services to some degree, the question is is it important enough to move it back to the MEP station to make it an accession type of screen. There's a lot of information that obviously needs to be brought forward on this issue before we systematically study that.

DOD has convened recently a panel to look

at accession standards and to try to -- I see Dr. Kelley in the audience -- to look much more scientifically at why we screen or what we screen for and whether or not it really has an impact on people's service, et cetera, et cetera. So that's very good. A lot of the methodology that we've used in prevention for preventive services we're now applying to accession physicals and periodic examinations and those types of things.

But certainly, this issue, I feel much more comfortable with this in light of some that we conducted earlier.

So that's really all I've got for you today.

DR. KULLER: Questions?

(No response.)

Just a comment, Mike. I enjoyed that. I think you mentioned one of your two major areas is the managed care which, of course under that and outside of the military, I guess, capitation. We're all thinking about around the country and the capitated type of medical care is a fiscally sound type where we can keep people well.

So I think going more into what we're

doing, we can do to help making this prevention along the lines of things you talked about and exercise and cardiovascular health, weight control, et cetera, would be very appropriate to -- you know, in the military I think it's expanded the model for outreach.

LT. COL. FALKENHEIMER: On of the issues that particularly General Anderson and General Roadman, both the current leadership in the Air Force, are very keen on is getting at some estimate of what is the appropriate, in quotes, proportion of the Air Force Medical Service budget that should be spent on health promotion and disease prevention to assure the maximal health and most efficient health care system. And we are actively looking at methodologies now developed by the Public Health Service when they went through the Health Care Reform exercise, at least to know what should be included in that count.

They tried to come at -- they came with the figure of 1 percent based on both population based and an individual clinical preventive services. What is the appropriate amount. And to the degree we develop a methodology in the Air Force and then

say here's what we're spending and we want to spend more, the biggest question comes because it's kind of like taking someone who's been a hostage for years and saying, "Now you've got a million dollars. What do you want to do with it?" He doesn't know what's on the market.

The prevention and public health community has been so underfunded that once you tell them, "We're going to double and triple your budget. What would you use it for?" Then you've got to start marshalling the arguments about what's the most effective way to spend that money.

But we want to push that envelope and particularly General Anderson is very keen on raising this up. He's been very concerned that many of the clinical issues have been divorced from the program funding and budgeting process and how do we infuse clinical expertise and a prevention focus into our budgeting process.

And so there's a meeting going right now, Strategic Resourcing, in Washington, with Air Force group staff people from all around the Air Force talking about how we do that better.

DR. BROOME: And that will include both

individual clinical preventive services and population based prevention intervention?

LT. COL. PARKINSON: Yes. Because our health promotion activities are under EPSG's budget, although it's really collaborative. We use other line items in the budget for health promotions. But yes, it will include both.

DR. GWALTNEY: I would propose one goal would be to offer periodic health risk assessment for everyone in the Air Force the way you're doing it here. I don't know what percent that is but that seems to me that's what the goal is.

LT. COL. PARKINSON: That is a goal. As a matter of fact, in many places we're moving toward that. I mean, essentially what we want to do is in the Health and Wellness Centers we're establishing these one-stop shopping. You heard Major Shell earlier talking about that.

The Health and Wellness Center is going to be the focus, kind of an adjunct to the clinic where we basically administer health risk appraisals and then basically have follow-up as the medical indications --

DR. GWALTNEY: Do you know what percentage

that might be, roughly?

LT. COL. PARKINSON: I don't know off the top of my head right now, sir.

DR. STEVENS: Just a comment on the screening for hepatitis B and C. There was a workshop conference that was sponsored by the Heart, Lung and Blood Institute and I think FDA in January looking at the issue of dropping surrogate markers from screening of blood donors. And in particular, ALT and anti-core. These were markers that were adopted as surrogates for hepatitis C before we had the C virus identified.

I think that group is recommending to drop ALT screening from donor input, not as yet anti-core. But it's also -- I'm just bringing this up because it's a reminder that anti-core itself is not necessarily identifying somebody with this condition. Most of those people will have anti-surface antibody and won't really have any risk for liver disease. So it's a little different from the antigen and anti-C.

LT. COL. PARKINSON: Right. I think we feel a little -- personally I feel that this is a program that we backed into because of the practice

of having recruit blood donation. Now that it's turned up on your doorstep, what do you do with it.

And so I think the right question is given that we do this, is there enough merit to moving it forward into the MEP station. I'm not convinced if there is really, because then we're chasing down even more red herrings than we perhaps need to sooner. So, at any rate --

DR. KULLER: You said now that you're going to keep track of people who were deployed. Is that just going to be the count that they were deployed or is there going to be some way of monitoring that they did get deployed, where they got deployed and under what circumstances?

LT. COL. PARKINSON: When I mentioned that 12 point plan before -- and please, any colleagues join in here -- that is all in here. I mean, the 12 point plan includes such things as identifying the cohort that deploys, basically collecting better in theater information about any variety of threats, including environmental, infectious disease, et cetera; locations of units; geographic tracking. It's really soup to nuts. The various things that we're now trying to catch up through the Persian

Gulf experience. All those things should be proactively built into the plan.

DR. KULLER: What happens to this data when the individual leaves the service or especially what happens to the data subsequently? Who's going to be the long-term keeper of the data on people who get deployed?

LT. COL. PARKINSON: I'm not sure that that's been talked about yet. And to be honest, we're still in a stage where that is clearly not something we've talked about.

DR. KULLER: I think that's a very important issue because in my experience in dealing both with Vietnam and later on in the Gulf, but especially with Vietnam, the experience was that the keeper of the data didn't know where the data was and didn't know how to use it. It think the same thing is going to happen again unless the keeper of the data has quality and knows what they're doing.

COL. TOMLINSON: I think there was a plan. We did discuss turning the data over to the VA. We will have it all on computer at that point with the systems and I don't think it will be thrown away. I think that that will all be kept where it could be

retrieved in the future.

LT. COL. PARKINSON: I would say given the current climate, I'm sure it would not be thrown away. I think we'll hold on to it.

DR. BROOME: Two questions. Are you considering collecting serum samples pre-deployment as part of that?

LT. COL. PARKINSON: We had long discussions about the need for pre- or post-deployment routine total force sera collection and what it was generally decided was that because of our HIV testing programs that we have a relatively good recent sera on all active duty members and that therefore the need for pre-deployment routine collection was basically -- we had a baseline. And we had baselines going back to the time they came in, I mean, essentially. So the maintenance and storage of sera in a sera bank is something we still need to work out the kinks, but basically we have the capacity to do that.

On the other end, in terms of post-deployment surveillance, the feeling was with improved in-theater surveillance and post-deployment surveillance, that we would draw blood and sera only

if there was an indication of a problem that would require such a thing. And to do otherwise, both in terms of the cost and the storage and even in a sense the unnecessary fear or even the logistics of how you do it, we couldn't justify it. And for that reason, we would do it as indicated clinically by the deployment information that we got.

DR. ASCHER: But you have follow-up HIV through the normal rules anyway. Sequential bloods at one or two year intervals, anyway.

DR. BROOME: Are those kept?

DR. ASCHER: Yes. Absolutely.

LT. COL. KELLEY: I think it was the July meeting when I spoke about the Army-Navy Serum Repository which is a contractor run repository out in Rockville, Maryland where we currently have banked approximately 15 million specimens. These are specimens that are accessed from the recruit-applicant screening program going back to about 1985 and the Army active and reserve component programs going back to the earliest days, and there are some Navy sera in there, too.

Prior to about '89, some of the sera are harder to retrieve because the data needed for

linkage wasn't computerized. But from '89 onward we do have our computerized data that allows us to take an individual and figure out what his serum number was -- numbers were. And that's a quite efficient system and we've been using it for a variety of studies and hope to see it used much more extensively in the future.

DR. STEVENS: Is that just the entry samples or is it also annual?

LT. COL. KELLY: No. For recruit-applicants, we have all the recruit-applicant samples. And then for the active Army, the current policy I believe is that they get tested at least every two years. Certain people would end up getting tested more often than that.

I'm not sure how frequently things are in the Navy, but we are banking Navy sera. I'm not aware that we have the force testing sera for the Air Force, but I do believe we have their recruit-applicant specimens.

LT. COL. PARKINSON: There are aspects of this that have to be shored up to make sure that we do meet that. Certainly the pre-, some baseline sera on every single person that might deploy.

CAPT. TRUMP: What we definitely have is samples so if there's a question, we can get controls and cases in controls or deployed and non-deployed and develop a study. I'm not sure we need to have them on every single person. The numbers are there to look at things in depth, if necessary.

DR. BROOME: The other question was on the managed care. Clearly it's a real opportunity to emphasize clinical preventive services but the other big driving force has been cost containment. Is that also a part of what you're all undertaking?

LT. COL. PARKINSON: Certainly that's the goal of the overall effort. My own person view is that there is an extended lead-in time. The country is divided up into 12 regions and the regions are coming on line with this and there are at least three different financing mechanisms that can be used to enroll patients in various odds and ends. And that is as much of a legislative mandate as it is anybody's choice. And that makes a little complicated, I think, to look at it in it's true benefit sometimes, in terms of cost containment versus quality outcomes, et cetera, et cetera.

So it's a huge system. I think we're the -

- you know, a Fortune 10 company and we're the second -- you know, named the largest if not second largest health care system in the world. And to bring that on line, change it from a fee for service type mentality to one which is managed care that emphasizes clinical guidelines, you know, capitated budgeting, best practices, it's a monumental task. And we're working on it as best we can, but it's a huge job.

DR. KULLER: Thank you very much. Captain Trump?

CAPT. TRUMP: Good afternoon. It's a pleasure to be here representing the Navy. I'm here on behalf of our Surgeon General Admiral Hagen and my more direct boss, Admiral Sanford.

On a personal level, as Mike indicated, things like the Persian Gulf illness and the Comprehensive Clinical Evaluation Program, deployment surveillance and the like, is keeping me busy and certainly at the Headquarters level are areas of major concern. And much of what Colonel Parkinson talked about for all those areas applies to the Navy.

What I would like to talk to you about in

my few minutes this afternoon are some of the other things that are going on more out in the field with our preventive medicine officers and the clinical providers out there. In many cases, the issues that this Board has gotten in the past when it comes to respiratory diseases, surveillance and control programs.

The first one I'd like to talk about is an investigation of an outbreak of acute respiratory infections that occurred among the recruit training -- at our recruit training center up at Great Lakes, Illinois this Fall. Commander Steve Hooker from the Navy Environmental Preventive Medicine Unit in Norfolk was the main epidemiologist involved in that investigation. They did find that there was a significant increase in hospitalizations for acute respiratory diseases that occurred in the period from August through October last year, and it was primarily based on hospital admissions for pneumonia, peritonsillar abscess and pharyngitis.

Thirty recruits were admitted with diagnoses of pneumonia, 10 due to Haemophilus influenza and four due to Group A beta meolytic streptococcus and 16 with no known etiology. For

the comparable period in 1993 there were only two admissions for those same diagnoses.

Similarly, there were admissions for peritonsillar abscess that increased from two to 21 in the three month period in 1994; 14 of those due to Group A beta hemolytic strep. And the admissions for pharyngitis that required in-patient care also increased.

The average recruit population in those two comparison periods did increase also. It went from about 5,000 in 1993, as the average recruit population, up to 8,000. And that's due to the consolidation of all of the Navy's recruit training at one training center at Great Lakes. We've closed the centers in Orlando and the center in San Diego has been closed also. So all of our recruits are up at Great Lakes, which historically has been a hotspot for infectious diseases for recruits within the Navy.

From a preventive medicine point of view, it's going to keep things interesting.

Because of the change in the denominator, though, the rates had to be looked at and they also increased. Essentially a tenfold increase in rates

of hospitalization between the two comparison periods.

Most of these cases occurred during the Summer, and as part of our streptococcal disease program at Great Lakes, the penicillin, the bicillin prophylaxis is stopped every Summer. It is not resumed until the 1st of October and that has worked well because it's been a time of relatively low morbidity.

During the Summer preceding the outbreak there was an average per week of seven recruits with Group A beta hemolytic strep pharyngitis per 1,000 recruits, compared to about three recruits per 1,000 per week in the previous Summer. The rate never exceeded the 10 per 1,000 cut point that triggers a more emergent bicillin prophylaxis program.

But with the onset of the outbreak was that October was also the time that the prophylaxis program is normally put in place. Bicillin was given and it brought the levels down and the number of hospitalizations down quite promptly.

There were some factors that were felt to be related to the outbreak that included the increase of the recruit population at Great Lakes

with the closures of the other training centers; the unavailability of adno virus vaccine, although at this point we have no confirmation that adno virus was a particular problem. They were reporting increased visits to sick call for respiratory diseases during that period of time. And also, the potential that this may be a more virulent form of streptococcus that was present at that time.

Commander Hooker and one of our residents in training are going back up to Great Lakes to do some follow-up to the earlier investigation and look at some of these other issues here in the next month or so.

Another streptococcal problem that we had in the past two weeks was a case of necrotizing fasciitis that occurred in the SEALS Basic Underwater Demolition Training Program which is out in California.

There were two cases of invasive streptococcal infections among trainees who were going through what is locally known as Hell Week at BUDS. One of those trainings had a necrotizing fasciitis of the leg that required extensive debridement and a second had an extensive cellulitus

requiring incision and drainage. And four others were hospitalized with less severe forms of streptococcal infection. And this is out of a group of 70 to 80 who were in the training program.

Hell Week is just a very extremely arduous and physically demanding training program that occurs after four or five weeks of physical conditioning that the trainees at BUDS are going through in preparation for the further training that will go on over several more months until they become Navy SEALS.

When they had these cases, the Hell Week program was stopped. All the other trainees received bicillin prophylaxis after cultures were obtained. It was thought that the index case may have been a trainee who was treated for a furuncle during he preceding week.

The preliminary study by Dr. Kaplan's lab on the two isolates from the necrotizing fasciitis case and the other of these were not the same type, but that is quite preliminary information and more work is going to be done out there.

Other work that's going on out in California is continued surveillance of the

pneumonia cases among Marines at Camp Pendleton. The Board has heard about those efforts in the past. Pneumococcal vaccine was administered in October 1994 with a subsequent decrease in incidence. And at some point in the future, the results of that intervention and the ongoing surveillance could be discussed in more detail here with the Board.

And Commander Greg Gray at the Naval Health Research Center and others out in the San Diego area are continuing their clinical trial of azithromycin and benzathine penicillin for preventing respiratory diseases. To date they've enrolled 1,106 Marine volunteers. There have been on severe reactions to either drug and the side effects with azithromycin have been minimal.

Commander Gray reports that the preliminary data from 262 Marines after two months of observation show lower rates for cough of one or more days' duration among Marine who are receiving azithromycin. But again, that's preliminary information.

One other investigation that took place during the same period of time was an epidemiologic investigation of adverse pregnancy outcomes that

were suspected to be occurring out at the U.S. Naval Hospital at Yokosuka, Japan.

In December 1994, Lieutenant Commander May from our preventive medicine unit in Pearl Harbor conducted what is a preliminary investigation because of concerns that there were increased numbers of congenital anomalies among newborns; there were increased numbers of spontaneous abortions; and that there was a potential cluster of fetal anomalies in pathology specimens from those spontaneous abortions.

In 1993 there had been three significant congenital anomalies. In 1994 in the first 11 months there were 10 significant or potentially significant anomalies. These were quite varied in their nature and their overall number and type did not exceed those that would be expected in the population.

Over that same 23 month period there were 150 or 12 percent of all pregnancies ended in spontaneous abortion. This again is less than the expected rate but during the three month period, June to August 1994, the observed number of 44 spontaneous abortions was twice what was expected.

The conclusions that were made were that the incidence of congenital anomalies among newborns were not higher than expected. That the incidence of spontaneous abortion was higher than expected in June to August 1994 but not during the preceding 22 months or subsequent three months. And that the incidence of fetal anomalies in pathology specimens was not higher than expected. And that really no conclusion could be reached at this point on the probable cause of the increased incidence of spontaneous abortions.

We're going to be doing a follow-up investigation in April after the infants who were born from the cohort of newborns who would have been conceived at the same time as those who were spontaneously aborted. Most of those infants would be born in the December to February period of time.

One other thing I would like to do during my presentation and hopefully can do in the future is give you a brief update on some of the research activities that are taking place at the Naval Medical Research Units. And this is in part triggered by Captain Steve Wignall who is the Commanding Officer out Naval Medical Research Unit

Number 2 in Jakarta, Indonesia.

Just providing an update, the Board or Board members have gone out to the overseas laboratories in the past to look at their research programs. Both NAMA and NAMRU have been involved continually with malaria research activities, surveys of p-thalcifrone and p-vivax resistant malaria that's resistant to chloroquine in Northwest --

They have been doing studies of co-therapies with chloroquine primaquine for chloroquine resistant p-vivax and found an 8 percent failure rate with using the co-therapy compared to a 65 to 80 percent failure rate when using chloroquine alone.

They are able to do a comparison study of mefloquine and doxycycline for malaria prophylaxis and irryangia among Indonesian military and found that mefloquine was 100 percent effective and doxycycline was 99 percent effective in that population, in an area where soldiers on placebo were experiencing 5.7 cases per man year of exposure.

They've conducted a malaria survey in

Vietnam in the Con Bin District where the six month attack rate is 77 percent. They feel that it may be an excellent site for future malaria vaccine and other prophylactic studies.

There were ketsial disease activities that include sera prevalent studies for murine scrub and fictyphus among Indonesian military who deployed with the U.N. forces to Cambodia and surveillance for scrub typhus in Indonesia.

They have also been very active out at NAMRU with empiric disease studies among U.S. military who are deployed to their region. They can conduct surveillance in collaboration with EPNU-6, with AFPREMS and with the Marine and Navy medical officers who are out in the field during exercise Balanced Torch '94 and Cobra Gold '94. Both of those are in Thailand.

During Balanced Torch, 47 percent of the 330 members who were surveyed reported diarrhea at least once during that one month deployment. Campylobacter is the most common isolate in 50 to 60 percent in both exercises and they are going to look at a pre-vaccine trial during the 1995 exercise to see if that's something that might be feasible in

that environment.

They've done shipboard studies during port visits in Indonesian ports, Hong Kong, Singapore, Kuwait City and Jabalil. Overall, less than one percent of the crew has reported to sick call with diarrhea during those port visits, but on a survey, 5 percent of the crew are reporting diarrhea on average after each port visit, although not having to go to sick call for treatment.

When they have looked at samples there, E-tech prevalence in stool samples has varied from 1 percent to 40 percent. They're also in the second year of follow-up of the 67,500 Indonesian residents of North Jakarta who have been vaccinated with a genetically engineered oral cholera vaccine, CBD103HRG. And again, they have completed the first of the three years of follow-up surveillance. And they've continued programs on the prevention of military HIV infection; dengue, in preparation for a vaccine test site; hemorrhagic fever with renal syndrome in their area; and hepatitis E virus studies.

And the final thing I would like to plug during my time is that next weekend begins the 36th

Navy Occupational Health and Preventive Medicine Workshop. It's going to be held from 4 to 10 March in Hampton, Virginia this year. It continues to grow.

Captain Barry, the CO of Navy Environmental Health Center is here with us today and he's the host of that effort, which we are encouraged that as it grows, it's also becoming more and more of a tri-service opportunity for people to get together and share experiences, not just from the Navy and Marine Corps side but from all the services.

That's all I have. Any questions?

DR. POLAND: The recruits at Great Lakes that had hemophilus pneumonia, were they untypable or type B?

CAPT. TRUMP: I don't have those -- that information. As far as I know, it was untypable but I'm not sure.

DR. GWALTNEY: Were those diagnoses made on expectorated sputum or trans-tracheal aspiration or blood culture? Do you have that information?

CAPT. TRUMP: No. I do not.

DR. GWALTNEY: Because I think Dr. Poland's question -- when you diagnose pneumonia, it's hard

to know how to interpret the results.

CAPT. TRUMP: Right.

DR. GWALTNEY: And while there's Group A strep pneumonia certainly probably would be real, the H flus would raise more question.

Was it possible to do viral studies during that period of time?

CAPT. TRUMP: We have not done those. No.

DR. FLETCHER: Given the streptococcal incident, have you seen any rheumatic fevers spreading of streptococcal --

CAPT. TRUMP: I don't have that information as part of the report and that is not something that's been a significant problem. I have an anecdotal report that we did have one case recently.

DR. FLETCHER: Of rheumatic?

CAPT. TRUMP: Of rheumatic.

DR. BROOMES: Were the strep from that outbreak studied and did you see any strep toxic shock like syndrome in the Great Lakes outbreak?

CAPT. TRUMP: The strep was not studied but we did not see any toxic shock in that group.

DR. GWALTNEY: How much larger is the population now that it's the only place for basic

training?

CAPT. TRUMP: The average population of recruits that's there at any one time has gone from 5,000 up to 8,000.

DR. GWALTNEY: And as I understand it, it's not a problem now. That it's been controlled with bicillin. Is that correct?

CAPT. TRUMP: Right. During October through May, all the recruits who are entering receive within the first two weeks, receive bicillin, all the male recruits. And then about four weeks later would receive the second dose, which would carry them through most of that period of time.

Those who are sensitive or have a history of sensitivity to penicillins receive erythromycin orally as an alternative.

DR. LEUPKER: You mentioned just very quickly an HIV prevention program. What are you doing?

CAPT. TRUMP: That was -- I can give you more details afterwards. I have a report from Captain Wignall. That's really looking at HIV in Southeast Asia and in some of the populations they

are working with there with the other militaries.

Yes?

DR. ASCHER: What was going to be your trigger for using pneumococcal vaccine at Great Lakes? In other words, when we got involved in San Diego, there were one or two sterile site infection positive pneumococcal diseases which raised a flag and got everyone convinced there was a fair amount of pneumococcal disease. Several of us said there must be more there and you must have some of it at Great Lakes, too. It's hard to diagnose sometimes.

CAPT. TRUMP: Right.

DR. ASCHER: So, I'm wondering in that -- whatever -- 12 or so undiagnosed pneumonias whether you had some pneumococcus and whether you shouldn't have used vaccine and whether you want to try to do it next year like we did at San Diego.

CAPT. TRUMP: I'm not sure that would be the first control measure that we would try.

DR. ASCHER: Well, you want to have a sterile site infection being your indicator system for pneumococcal disease. I wouldn't like that if I was a recruit.

DR. BROOME: But, you know, I attended an

AFEB meeting, oh, probably five plus years ago when somebody presented the information on episodes of pneumonia otherwise undiagnosed during the recruit period and there was a fairly, not surprisingly, substantially elevated number. And, of course, you don't know what they are. But to me, the thing to do would be to do a control trial of pneumococcal vaccine. You know, the way to find out if there are pneumococcal is to see whether you have any impacts from the vaccine.

DR. ASCHER: I was thinking we'd do it next year.

DR. BROOME: But you might consider doing it recruit wide.

DR. ASCHER: Yes. That's what I'm saying. Exactly.

DR. BROOME: Yes.

COL. TOMLINSON: Any other questions?

(No response.)

CAPT. TRUMP: Thank you.

COL. TOMLINSON: Colonel Frank O'Donnell two weeks ago replaced Colonel Rick Erdtmann in the Preventive Medicine Consultants Division at the Office of the Army Surgeon General and he now will

be the Army representative to the AFEB.

Colonel O'Donnell, for the last 4-1/2 years has been assigned to Walter Reed and has spent several months in Saudi Arabia during the war.

Colonel O'Donnell.

COL. O'DONNELL: Good afternoon. It hasn't been two weeks but 10 days that I have been in this new job.

(Laughter.)

And I'm going to milk that for everything it's worth today. I did on the basis of my six or seven working days thus far, did select a few topics which I either knew about myself or felt -- or picked the brains of some other folks I thought I would mention.

Colonel Tomlinson gave me my first intro. I did replace Colonel Erdtmann as the Preventive Medicine Staff Officer at the Army Surgeon General's office. He's actually been kicked upstairs. His title I believe now is Director of Health Service and the Preventive Medicine person, myself, I report to him, although I understand he anticipates an assignment as a commander of a hospital this Summer.

Colonel Tomlinson left the Office of the

Surgeon General where he served as Disease Control Consultant. He's now at Walter Reed where he's the Chief of the Preventive Medicine Service, filling in the vacancy created by my departure. And I guess at the moment it's fair to say you are still the Disease Control Consultant since a successor has not been named.

I did want to mention a few things about reorganization within the Army Medical Department and its impact on preventive medicine. I'm not sure if you've heard this before. Does any of the Board members recall hearing how the Army Medical Department was reorganized?

I don't want to belabor this point but -- you've heard?

How about the rest of the Board? I'll take a minute or so.

Basically, what's happened at the urging and the initiative, perhaps, of our new Surgeon General, Lieutenant General LaNoue, the AMED, as we call it, has been reorganized.

To make a long story short, what was once called the Health Service Command in the Army, which was the operational wing of Army medicine in the

United States, has been renamed the U.S. Army Medical Command. It still exerts an operational function and exercises command and control over all subordinate medical organizations within CONUS and Panama and Hawaii. And perhaps some day we'll actually exercise operational control over some far-flung AMED units overseas.

However, as part of the reorganization, practically what's happened is the Army's Medical Research and Development Command, which is now called the Medical Research and Material Command, has now fallen under the command and control of this Medical Command. It previously fell directly under the Army Surgeon General.

Furthermore, the veterinary and dental professionals have essentially been broken out into what we would call stovepipe organizations with their own separate veterinary and dental commands. And then lastly, a major impact has been the creation of what we call HSSA's, which is basically an acronym for regional commands. And the Army has seven. I believe it's seven regional commands throughout the continental U.S. and they in turn are intermediate command and control organizations which

control subordinate medical centers or what we call medical department activities, community hospitals in their geographic regions.

Those intermediate HSSA's or regional commands are something new but I think part of the whole initiative is sort of the powering down principle. In essence, to reduce the span of control of the previous Health Service Command and to in theory at least provide a more manageable span of control and let the Medical Command at the highest levels of this organization to really start to kind of look upwards and to play a greater role in terms of crafting the policy and big picture kind of organizational functions.

With the -- enough said about that. But one other organization which comes directly under the Medical Command is what the newly created organization called Center for Health Promotion and Preventive Medicine. It sort of fell in upon what used to be called the Army's Environmental Hygiene Agency and that organization perhaps make up -- well, I'm not sure. Let's say 75-80 percent of the strength of the new CHPPM, as we call it, Center for Health Promotion and Preventive Medicine.

Some felt that this CHPPM represents the Army's analogy to the Centers for Disease Control in an attempt to create a center of excellence where programs in prevention and health promotion could reside in many ways like the Centers for Disease Control, although by falling in on the former Environmental Hygiene Agency it also assumes or continues some missions which one might say are a little bit more environmental than they are classic preventive medicine.

Colonel Joe Gaydos who's here today, he's, I believe, a senior physician, preventive medicine physician on the staff of the CHPPM, and you'll hear more about that as time goes on. And he'll be talking to us tomorrow about adno virus vaccine and in the Department of Defense, really. And I just want to sensitize you to that issue today. That adno virus vaccine is an issue and he'll describe that more fully tomorrow.

One other impact of the organization in the Army Medical Department is that in the old days, shall we say, the Office of the Surgeon General where I am now, had a staff of about 12 professionals, several physicians, the Occupational

Medicine Consultant, the Preventive Medicine Consultant and the Disease Control Consultant, as well as a number of Medical Service Corps officers, each representing the various technical specialties within the general preventive medicine career field.

And in turn, at the old Health Service Command, now the Medical Command, there were about a dozen counterparts, if you will, sort of a matching set of professionals, also serving the same technical areas and serving a staff function at that level of command and control.

Well, that total of about 25 bodies dedicated to the preventive medicine mission in the Army in the Army Medical Department, after the reorganization has been reduced to 11. And of those 11, nine of them are at the Medical Command. So in fact, at the Army Surgeon General Office, there will remain two out of the former dozen or so. And those two will be myself for as long as I can hold out, I guess, and a Sanitary Engineer Consultant. Currently that position is occupied by Colonel Bob Fitz.

It's this downsizing, if you will, consistent with the downsizing of the Department of

Defense in general, certainly with the Army, and it forces upon us in the Surgeon General's Office with a re-look at what exactly is our role. And I'm new enough to the job that I'm not going to attempt to tell you what that role is. I'll probably know by the time -- the next time the AFEB meets.

But suffice it to say its role and its function is going to change. And I believe Captain Trump and Colonel Parkinson alluded to their preoccupation with tri-service endeavors and working with DOD Health Affairs. And just in my first 10 days or so, I found out that is a big ticket item on my agenda for the future.

But suffice it to say at the level of the Surgeon General's Office, preventive medicine staffing has gone way down.

I do want to mention that the senior preventive medicine physician at the Medical Command is Colonel Ben Diniega, who's sitting back there in the audience. And I'm sure many of you know him already. He's been there since the Fall. And if you really want to know what the Med Com does and what he does there, I suggest you buttonhole him during the breaks.

One thing which Colonel Diniega has initiated which I think will help in the context of reduced manning of preventive medicine headquarters, he's initiated a series of monthly video-teleconferences amongst the senior leaders in preventive medicine in the Army. It includes both folks at the Surgeon General's Office, his office, the Medical Command, these regional commands, the overseas preventive medicine leadership and the folks from CHPPM.

And I think the first one was held in January. Is that right? January. And from my vantagepoint, I thought it was very well done. A very busy two hours indeed, but very, very useful in terms of enhancing the communication between the various players in the preventive medicine career field.

A couple of other topics I just want to mention briefly. With respect to the situation with migrants in Cuba, my predecessor didn't mention that so I'll just give you a few tidbits which I've been able to glean in my brief time.

As of the 2nd of February, there are approximately 20,000 Cuban migrants residing at

Guantanamo Bay. And you've probably seen in the news some of the problems that presents. There are also about 6,000 Cuban migrants who are in Panama.

The medical support, the joint medical support being provided by all three services to the population at Guantanamo is about 634 people, total officers and enlisted. And they're dealing with some very fundamental problems of not only sanitation in a very, very crowded environment, but also the provision of health care services to a population which I guess by definition is impoverished, suffering from many of the difficulties of living in poverty and crowded living conditions, with perhaps marginal sanitation, as well as with some of the medical problems they may have brought with them from, in this case, Cuba.

The other statistic which I just care to mention to you to kind of give you a flavor of some of the problems -- two statistics. One is the cases of active T.B. that have been documented to date amongst that population has been about 150. One hundred and sixty, I believe is the number.

And the other number which I thought was interesting was that amongst the two populations of

foreign nationals who have been at Guantanamo, amongst the Haitians and the Cubans, there've been a total of about 200 live births in Guantanamo Bay. And again, just to kind of punctuate some of the kinds of medical problems facing the folks providing medical support down there.

Just a few words about the situation in Haiti. The American presence there is about to be reduced even further and the United Nations is going to bring in -- at least 10 different countries are going to contribute forces to continue the United Nation's efforts in stabilizing the political situation in that country.

I'll just mention in very general terms that the situation with the first cases of dengue amongst our forces has really quieted down. I'm not sure I can give you a number but there was a flurry of cases back in the late Fall, but that situation has quieted down.

Chloroquine prophylaxis is SOP for American forces in Haiti and appears to continue to be a successful form of prophylaxis. There have been occasional cases of falciparum malaria amongst non-U.S. personnel but I'm told, at least amongst the

latest few cases, that those people responded to therapy with chloroquine itself. So, so far, so good.

One concern about the -- two concerns about the arrival of military from other nations who are going to take over this U.N. mission. One is the issue of the malaria. Many of these countries -- three or four at least who are providing forces to the U.N. force are countries which are malaria endemic themselves, some of which have chloroquine resistance falciparum malaria. So there's at least a theoretical threat that it's possible there will be introduction of chloroquine resistance into Haiti.

The other side of that picture is apparently transmission of malaria in general in Haiti at least at the moment is very, very low. So, given hopefully a very low prevalence of carrier state of malaria and a very low rate of transmission of malaria from carriers to new cases, maybe chloroquine resistance will not be -- will not surface. But it's a theoretical concern at this point.

The other aspect which was mentioned to me

is that these U.N. forces are going to disperse a little bit more widely throughout the country than has been the case thus far. They'll be moving into geographic regions which have not been well characterized in terms of endemic disease threats. So our folks who are providing the lion's share of the preventive medicine support have some unanswered questions about the endemic disease threats in these new areas. And there are also unanswered questions as to how well these new forces will attempt to sustain levels of field sanitation which will keep them out of trouble.

That's important to us, even though the remainder of our -- shall we say our combat arms types, American combat arms types, may be departing Haiti in large measure, the medical support which will be provided to the United Nations forces will continue to be American medical support. And so to the extent the preventive medicine fails, to the extent that there's an increase in the incidence of disease amongst the U.N. forces, the impact is going to be borne by our U.S. medical hospitals which are providing medical support down there.

One other item I want to mention is

something called the Medical Surveillance System, which I had hoped you had been told about before. Does this ring a bell with anybody on the Board? In essence it is a new reporting system for diseases of reportability. Let's put it that way.

The Army had a time honored method of recording diseases, primarily diseases but also injuries and other events, outbreaks, which were of a public health or command significance and it was what we used to call the MED-16 system. And it was said to be a telegraphic system.

In essence, you want to collect the requisite information for reportable disease and the regulations said turn it over to an administrator, patient administration type, or registrar, if you will, and have them send in the report. That never worked.

Preventive medicine folks, epidemiologists, should never turn over such information to records types. I mean, they'd send the report when they got around to it. But the whole design of the system was telegraphy, a fast method of communications way back when the system was devised.

Well, finally, the system was superseded

this year by what we call the MSS, the Medical Surveillance System. And in essence, it depends upon modem transmission of relevant information about a long list of reportable diseases, most of which would correspond to the reportable conditions which most state and federal agencies would think are reportable either by law or by good sense.

We've got some additional ones which pertain particularly to the military. And in essence, if you've got one, if you find one in your medical treatment area, you fill out this very handy-dandy computer friendly report and it takes about two minutes if you've got the data at hand, and then you essentially say "transmit" and the program transmits. It dials up the receiving number and downloads -- or uploads and downloads the data to the computer at the Walter Reed Army Institute of Research, which is the central repository, and hangs up and returns you to the user screen.

I've used it for very many reports during my time at Walter Reed. It works well. And I haven't had any recent feedback from those folks but it's my impression from the bulk of Army preventive medicine, they were overwhelming these folks with

reports. It's actually turning out to be a very effective system.

A large part of the numbers are due to the fact that people are reporting sexually transmitted diseases and there's a lot of that. But from my vantagepoint at Walter Reed, we're reporting a lot of other curiosities, not only some pathogens but all military cases of leishmaniasis end up at Walter Reed. So we've dutifully reported each one of those.

And I suspect that perhaps in the Fall at the annual preventive medicine meeting when we'll get an annual summary of what's been coming in, I look forward to that. I'm sure the database has accrued some very interesting information.

So, the summary data should be very interesting; hopefully, much more useful than the old system it replaced. But more importantly, it may actually turn out to be a timely system in the sense -- it was just last week, it turns out, that the folks who were collecting this data are sending to the Surgeon General's Office a daily summary of the previous day's reports. And I'm sure 90 percent of the time they're sort of not terribly

interesting. But the one that caught my eye last week did catch my eye because of three cases of people with carbon monoxide intoxication, all from the same place.

And that definitely caught my eye and it happened the day before. So I think it subserved a need in the sense that we at higher headquarters were alerted to this event and I tried to make sure that others who ought to know about this did know. And, of course, further inquiry will take place.

So that's a new, exciting development, taking advantage of new electronic technology, which I think is finally subserving a need which we in the field of preventive medicine/epidemiology have always recognized. Information is power, if you will.

Now, what kind of power? Well, the power to do good things. I mean, that's really all it's about. And I think this is probably a technology which will be very useful in that regard.

That's all I've got to report. If you want me to say anything else, I guess I don't know any better at this point, so I will plead ignorance.

Anybody got any questions?

DR. WOLFE: I share your concern about that theoretical risk of importing chloroquine resistant malaria into Haiti. There should be other interested parties, such as PAHO, CDC, maybe USAID. And conceivably, if it doesn't sound like pie in the sky, there is something that could be done in terms of maybe screening these people coming in from malaria endemic areas and treating them before they get to Haiti with something like Fansidar, which is simple and well tolerated in treatment dose, if they're not self-allergic. Perhaps Halofan, which again should be safe in a young, healthy individual. Mefloquine might be a bit difficult relative to the other two. And perhaps the Army should take some initiative in at least contacting these other organizations to see whether somebody might get something mobilized before it might be too late.

COL. O'DONNELL: Again, I plead ignorance as to whether or not or what kinds of coordination may have occurred.

DR. WOLFE: Probably none. That's why I'm raising the issues.

COL. O'DONNELL: I wouldn't be surprised in the least, I certainly would agree with your

suggestion. Now, somebody's here from CDC; right? Know anything about this?

DR. BROOME: I'm not aware of any particular discussions but I think it would be a good idea and I can help put you in touch with the folks at CDC and PAHO. I mean, obviously the issues of jurisdiction in the military are not totally trivial, but it seems like we ought to be able to put together the technical expertise and then talk about what are the logistic feasibility issues.

COL. O'DONNELL: Yes, sir.

DR. KULLER: Two questions. One, a lot of the troops are going to be coming back from Haiti. What is the situation with regard to tuberculosis? And second, I was rather interested in -- I guess you saw this in November. In the Washington Post there was an article that dealt with CDC's concerns about GI's returning from Haiti, that they have dengue and the possibility, because there were mosquitos in the United States, it says here they might start transmitting dengue in the United States.

Now, it's a little bit worrisome because the statement is made that you can introduce virus

into an area where mosquitos occur. There are very few places in the United States that mosquitos don't occur. Somebody reading this would be terrified.

Just because of a previous experience with the Gulf War and others, is there a plan to handle the issues that may occur with regard to the troops now returning from Haiti and somebody coming up with this idea that we're suddenly going to see, quotation marks, some clinical dengue or something?

COL. O'DONNELL: I'm afraid my response will have to be a general one at this point because I've not been working the issues. I had sort of a parochial span of view prior to 10 days ago.

My feeling is, -- how is that going to play out? Well, first of all, we are very sensitive to the issue of dengue occurrence amongst our folks. And I think the scrutiny with which people with febrile illness, the scrutiny they receive when they go to the MTF's in Haiti is fairly close.

At the moment, -- somebody can correct me. At the moment, we are not attempting to do dengue serologies from bloods taken in Haiti. The qualitative feedback I got from somebody who's down there right now is that they've not been -- they're

really not sure about a lot of these febrile illnesses they are seeing, but if any of it is dengue, it's a very atypical presentation. It's not as severe I guess or typical in terms of symptomatology. This was their experience in the Fall.

Is this a major concern nevertheless or for the long haul to the United States? My knee jerk reaction is yes, of course it's of concern. There is a -- and with respect to the issue of T.B., I have at least been the recipient of documents from the Office where I now work that suggest that anybody who returns from Haiti needs to go through a medical basically clearance process or at least a medical scrutiny at their home station. That would include a T.B. skin test.

And I believe the proviso is we needed to have it three months after -- the skin test -- three months after their return. In terms of the rest of the review, I believe it was more of a careful history and a PRN evaluation of the soldiers.

Colonel Tomlinson, you may be able to shed some more light on this.

COL. TOMLINSON: Yes. On dengue, it was

determined that individuals returning home based on the period of time of viremia during the illness, that it takes them a few days to get home and only those who had just been infected would still be viremic by the time they returned.

The mosquito population was very low at that time around Fort Drum where most of the individuals were returning to, so it certainly was -- we were asked to answer this question. It was theoretically possible but highly unlikely that dengue would be introduced to this country.

And in speaking of the risk of malaria or dengue, that same risk would apply to civilian travelers also. And other than along the Mexican border, I don't think we'd have too much of a problem with malaria being introduced into this country.

So from a practical standpoint, we don't see it as a big problem. Of course, tuberculosis, we have seen some T.B. converters after returning from Haiti; likewise from Somalia. We have not seen any active disease in any soldier returning from these foreign deployments but they are checked. It's part of their post-deployment surveillance that

they return three months after getting back home for T.B. skin testing.

DR. KULLER: I would strongly -- I'm just reading again. Somebody sent this to me from our university as a warning. And it says, "CDC says GI returning from Haiti may be susceptible to dengue fever." And then underneath it is somebody from CDC warning about the fact that there could be transmission of dengue in the United States, which as you said, is extraordinarily unlikely.

But somebody reading this in the Washington Post, especially with the authoritative statements here, we can start all over again with another cycle of all kinds of problems.

So it seems to me that maybe since CDC is in the middle of this, maybe CDC through the morbidity, mortality surveillance in the weekly reports could suggest to them putting out something about what's going on in Haiti and also make sure it's known so that we don't start all over again with maybe yes, maybe no, perhaps or possibly, because we're going to wind up with another catastrophe on our hands for sure.

DR. WOLFE: Dengue was endemic in Somalia.

Dengue has been endemic in Puerto Rico for many years with lots of Puerto Ricans coming into the country. Dengue has been endemic in Mexico, the Caribbean, Central America for the last few years with many, many tourists coming in. We do have occasional cases of dengue imported but there's been no spread. And I really would not put any great emphasis on this except to try to quiet down that article.

DR. KULLER: I agree with you. But it says here clearly -- I mean, Dwayne Googler, who's Director of Ecto-borne infectious diseases announcing that there's an increasing risk of physicians seeing severe dengue in the country but also increasing the risk of introducing the virus into areas where mosquitos occur because mosquitos can transmit the disease to others. And that basically, -- in my mind, mosquitos occur everywhere in the United States.

DR. ASCHER: But there are also mosquitos and mosquitos. Not all mosquitos carry dengue.

DR. KULLER: That's right. But somebody reading this -- and it's obviously -- I mean, it doesn't -- it's not coming out of somebody's back

yard, so I mean, I think you're absolutely correct. I think the point or concern I have is that anybody who comes back from Haiti now who starts complaining of respiratory infections or not feeling well or tired, whatever else is left, we're going to start all over again with either they just have dengue or -- especially if somebody in their family also comes up with a respiratory disease. It will be a mini-dengue epidemic that doesn't exist.

COL. O'DONNELL: I think the principle vector in this hemisphere with Haiti is Egypti, isn't it?

DR. ASCHER: Yes.

COL. O'DONNELL: And we've got plenty of that in the United States. But I think it cuts off just above the Mason-Dixon line or something like that.

DR. ASCHER: Alopictus is the --

COL. O'DONNELL: But alopictus is here and it's probably in a lot of -- well, it's probably sporadically distributed and it will work. But again, I think we got lucky perhaps that the soldiers went back to Fort Drum in December when there weren't too many mosquitos, and I think with

Haiti's Egypti being so prevalent throughout the United States in the warmer months, we've already passed the test of life, if you will, with the other travelers who've returned presumably, from getting the virus.

We've passed that test. The only way we could change that perhaps is we introduce gigantic numbers of people carrying the virus during the warm weather season, but again, I don't think that's likely to happen, given the experience thus far.

DR. GWALTNEY: I'm not an expert in tropical medicine but I just returned from Puerto Rico last Monday and I spent the morning with a group of Puerto Rican physicians. As Dr. Wolfe points out, there's a huge traffic of Americans back and forth to Puerto Rico to fill up those cruise ships and there's going all the time. And Haiti's right next door and they've had a big epidemic of dengue in Haiti this year. Right now they're in a drought. They're out of the dengue season. So this is a good time to bring the soldiers back.

But it's ridiculous to say that the troops are going to bring it back when all these civilian tourists are a much large risk of bringing it back,

if it were going to happen.

DR. POLAND: I wonder if you could brief us at all about what I think I read where one or two deaths among troops at Fort Bragg, I think.

COL. O'DONNELL: Of?

DR. POLAND: Rangers.

COL. O'DONNELL: You mean the hypothermia deaths? Well, actually -- I mean, I could tell you what I know, which is probably not a whole lot more than what's been in the press.

Four Ranger students, candidates, succumbed to what was apparently hypothermia. I believe it was last Wednesday. And I think the accounts that I heard in the newspapers were apparently corroborated by what I heard through the military channels, which wasn't much. But there were four deaths. They were rather casualties, if you will, from hypothermia.

The circumstances leading up to it, as I understand it -- and again, I think this has been in the newspapers. Basically, the exercise, the training, if you will, required these trainees to find their way through a swamp. And I don't know what the distances were.

Traditionally, I'm told this water is knee

deep or so. Because of recent precipitation or something the water was considerably deeper, waist high up to mid-trunk. Water temperature was 52. The SOP there says we will lot let soldiers in the water when the water temperature is 50 or below, so it was above the standard, but actually the degree of emersion was greater than they were used to or what they could have anticipated.

And there were survivors who apparently definitely had hypothermia and there were some others who succumbed. There is a -- and I think that's pretty much everything I know. In a circumstance, an event like this, there would be obviously a very detailed investigation. The investigation, as I understand it, is being headed up by the Army Safety Center. They've got the horsepower to do this.

They will be assisted by both the -- I know an Inspector General's Office, and I'm not sure at which level of the command. It may be the Department of the Army will be participating in this. And undoubtedly the medical input will come from U.S. Army Institute of Environmental Medicine -- Research Institute for Environmental Medicine at

Natick, who've got a good deal of expertise in the area of heat injury/cold injury, et cetera., including emersion type injuries.

And matter of fact, the Rangers who go through this training have been extensively studied by the folks at USARIEM. And I found out, as I was trying to do my home work, what I found most interesting is that what happens to solders who go through Ranger training. And I believe it's a four week training course and if you pass you get a Ranger tab to wear on your uniform. And it's very rigorous. And by the second week or so, some major decrements in body weight have occurred, some readily discernible decrements in immune function have occurred and -- did I say weight loss?

And by the end of the four weeks, weight losses tend to average 15 to 25 percent of body weight. And part of what goes along with this physiologic change apparently is at least on average a radical decrement in glycogen stores in the body, presumably in muscle glycogen. And when you don't have any muscle glycogen it's very hard to shiver. That's the way it was explained to me.

So, that the -- and this was their four

week. So, physiologically, they were most vulnerable, shall we say. And in the environmental circumstances as I've heard them, certainly it's not surprising that there may have been casualties. But whether or not it was predictable or expected or preventable or should have happened, I don't know. I think there are more facts to come. But that's probably the limit of what I know about what actually occurred.

An Army expert who I consulted on this says when people die of emersion type, wet type hypothermia, it's probably ventricular fibrillation which does them in. And I found that very interesting because I didn't know this. And apparently the problem is your purkingje system is paralyzed when your heart temperature is that low. So circulation is sort of -- you know, electrical transmission is through the non-purkingje system which makes one very vulnerable to fibrillatory episodes, so I learned.

I can't answer any more questions about it. I think I've told you everything I know.

DR. KULLER: Any other questions?

DR. ASCHER: Last one. Regarding your

reorganization issues, I'm an active reservists, as you may not know, but everyone else has heard ad nauseam. And subsequently to our last meeting we had our debriefing of the reorganization of the Army from the reserve standpoint and some interesting things were stated, which is that two things are going to happen, which is that the units that are not prepared to go are going to go away and that the total force is going to rely more heavily on the reserves. And these are factors that we felt played significant role in some of the Gulf War syndrome problems.

And the good news was that they seem to have some perception that some people were really not prepared to go and that they ought to get out and that some of the issues of being prepared was something people ought to think about. And the other thing they announced, believe it or not, that if you came back from reserve deployment and had a problem, there was a phone number to call.

And I asked the question, is this something that didn't exist before and there was dead silence. So a reservist that comes back with a problem doesn't have to go to the VA. They actually now

have a place you can call. He didn't know the number, but he was going to get it for us.

(Laughter.)

Next time, I'll tell you the number.

DR. KULLER: Who's at the other end of the line? That's the critical variable.

LT. CDR. ARDAY: I made overheads. It may or may not be to my benefit. It's also late and it's very hot, so I'll be brief.

I think Colonel O'Donnell provided me with a great segue talking about the end of the MED-16 system, because the Coast Guard is still using what is the equivalent of the MED-16 system and that's what I was going to talk about this afternoon.

We have analyzed our huge amount of reports that we received last year, --

(Pause to adjust overhead slides.)

We have a passive surveillance system as a standard and it's based on what we call disease alert reports which essentially are very similar to the Army's MED-16 system. And we have, according to the regulations, the reportable diseases include individual case of the standard infectious diseases that most people are familiar with.

And the Coast Guard also asks for reporting of a whole list of occupational illnesses or poisonings. It doesn't include injuries. Injuries are in a separate system.

It also requires the reporting of outbreaks that affect readiness or that affect another unit or the community. That's a judgment call. And also that are, as I used on the slide, quote, hot. In other words, the press says it's in the interest of the press, it's of interest to headquarters, so on and so forth. Again, something of a judgment call.

We're support to report epizootic diseases if we encounter any of those. If any Coast Guard vessel is placed under quarantine in a foreign port, that's reportable. And then the wonderful "other," which includes, again, anything that the local medical people feel would be appropriate for reporting.

Last year we had 27 reports received at headquarters and these include -- well, that's what you see on the pie chart here. We have the percentages here. There were eight cases, or 30 percent of the cases were sexually transmitted diseases; four or 15 percent were HIV sera

conversions; four were cases of infectious hepatitis of various sera types. I know hepatitis A is on the agenda here. I believe two of them were hepatitis A. There were eight cases of GI illness, mostly infectious diarrhea, and three others. Note the large number.

Pardon?

DR. ASCHER: How many Coast Guard members?

LT. CDR. ARDAY: The Coast Guard population? Well, the denominators are questionable. Let me bring -- use the next slide, so we'll get you the -- why the denominator issue.

The Coast Guard is 38,000 going down to about 35,000. We're in the process of downsizing right now, so the active duty Coast Guard population is very small. But of those 27 cases, only 17 were among active duty Coast Guard, about 63 percent. Five were among dependents, 19 percent. One among reservists. One was a recruit pending accession, and then we had a couple of cases from the Army and one from the Navy. Just happened to walk into our clinics and were diagnosed there.

So the actual denominator is probably anybody's guess. I have to add to that that our

clinics serve only about 50 percent of our active duty Coast Guard and dependent populations. We are so thinly spread across the country that in our many locations we will rely either on other local DOD facilities or civilian facilities which we have contractual relations or provider organization type relationships that we've set up in some areas to provide that care for our Coast Guard personnel and their families.

These were the cases that came to mind as being of interest during the last year, the ones that we had time to look into, I guess, is another way of putting it. There was one case of bacterial meningitis which is originally reported as having been on a cutter that was involved in the alien migrant interdiction operations and it was thought perhaps to be transmitted that way based on the original clinical diagnosis.

However, there were some problems with this. First of all, the individual was given antibiotics presumptively before evacuation from the cutter, so all cultures of cerebral-spinal fluid were of course negative. The individual's clinical course didn't really follow an acute bacterial

meningitis and he had a very prolonged course. And after further work-up the discharge diagnosis was essentially that he had probably aseptic meningitis overlying neuro sarcoidosis which was probably the reason for his encephalitic picture.

There were four cases of HIV serum conversion reported. Two were among active duty Coast Guard members. One case was in a Coast Guard reservist and one case was in a recruit-applicant.

I need to mention when I talk about HIV that the Coast Guard, unlike the rest of -- well, unlike DOD, of course. We're Department of Transportation -- does not do periodic screening of its population for HIV. We only screen based on clinical presumption, a recent case of STD or something like that, or as required for transfer outside of CONUS.

We are going to revisit this issue sometime in the next few months and look at whether we should reintroduce periodic screening. But I don't know what our caseload in the previous years has been. I do know that it's been less than four. The four that we've had this year has been higher than the previous two years, so we haven't had a lot of HIV

discovered. But of course, if you're not looking for it, it's hard to discover it.

And there was one outbreak of some interest during 1994 and that was four cases of shigellosis that occurred in four dependent family members, all of which were stationed in the New York City area. I believe they acquired it actually while they were on vacation in Orlando, Florida, and that's about all we know about it. They were culture confirmed. It was reported to the Florida folks, but the Coast Guard didn't do any particular follow-up on it and there was no transmission that we know of.

That's pretty much all I have, if anybody has any questions.

DR. PERROTTA: I'll ask you the question I was trying to get Colonel O'Donnell to answer. And actually, it probably deserve some attention by all four services. And that would be for the Board and perhaps for me to talk a little bit about -- maybe not now but at some other time, the reporting of conditions that you find on your bases with the local and state health departments.

Florida probably did the outbreak investigation with you or for you and that's what

state health departments are supposed to be doing. Obviously, we could probably help you more and we might be able to help some of the larger services, but working in the state health department, one of the bigger issues I deal with is ways to collect information about the cases that have an impact on our community.

And as somebody said, mosquitos and other things don't necessarily stay behind the base walls.

I was wondering -- maybe that's not for discussion right now, but I'd like to hear something about whether or not there's a standard operating procedure for reporting.

COL. O'DONNELL: Well, I could respond. I think the answer is pretty clear. I think it's been tradition, if nothing else that at least DOD agencies follow the dictates of the local jurisdiction's law. And I know, having come from Walter Reed, we follow D.C. law, which is basically report, in the case of D.C., it was AIDS defining conditions. Virginia and Maryland were different. But we were in D.C. and we followed their law and we reported to them.

We had a copy of what D.C.'s reportable disease were and basically just followed that. I think there was nothing controversial about it. If it doesn't happen it's because the local DOD preventive medicine service hasn't found out what they're supposed to do. I think it's more a matter of incomplete performance of duties rather than any principle.

I think in general we're committed to following the laws of the local jurisdiction.

DR. BROOME: But depending -- as you get these automated reporting systems, it isn't trivial, but you can imagine how much easier multiple delivery or notification to local jurisdictions. I mean, sometimes, like the meninges reports eventually would come to CC for the national surveillance. But I think it was relatively haphazard.

COL. TOMLINSON: That's how we sold our program, is it's really going to be of help to that preventive medicine service at the local hospital because that same -- especially STD's which you have a lot of. And other things could just be reported right off of our system.

DR. BROOME: Yes.

DR. BAGBY: -- I would second his suggestion that we might have a discussion of it at some time in the future because as an immediate past state health officer, I saw one development in one state that really worked. The problem is that the principle is there and even the regulations maybe are there but the local base commanders or the local preventive medicine people may not really know about it or may not have it emphasized to them.

But the Governor of Missouri set up a -- the former Governor of Missouri set up a civilian/military coordinating council and we had all the military bases in Missouri represented and all of the department heads of the state that had some relationship to any kind of occupation. And, of course, I represented health. And through that council we got excellent cooperation but it was a matter of bringing it to the attention of the local bases. And I think that's something that probably could be used anyplace to good advantage.

CAPT. TRUMP: For the Navy, our policy is very -- the policy is that you report to your local jurisdiction. We're revising some of our guidelines

for that and really trying to make that very clear that that's actually the primary responsibility. That especially with more managed care and other -- CHMPPS and other courses of care, we're only seeing a small part of our population, especially the dependent population. And we're trying to focus more on what the military reporting requirement is for active duty. Your other responsibility is to report locally.

And hopefully, that word will get out. The suggestion from over there may be the solution that's needed in some places. I think a lot of it depends on how good a relationship there is between the local health department and the base health department.

DR. KULLER: I think we're going to have to go on.

LT. COL. PARKINSON: Just very -- one of the things I talked to our IG about, which goes around and inspects our bases, is there's a question I want them to go out when they go out to the Aerospace Medicine Squadrons and our Public Health Officers: When was the last time you met with your local health officer; what is his or her name; what

meetings do you have in conjunction with that? You know, basically, do you sit on their infection control committee or vice versa, to operationalize it at a working level. Because it really is a personal interaction as much as it is a regulatory or statutory thing.

DR. KULLER: Colonel Leitch?

COL. LEITCH: I think Commander Clifford can be first to talk.

DR. KULLER: Okay. Commander Clifford, are you going to go first?

CMDR. CLIFFORD: Good afternoon. It's a pleasure again to be invited back, and particularly to Utah.

What I thought I'd do today is just give a very brief overview of where we are, or perhaps where we're not, with the Persian Gulf illness in Canada.

As expected, there's been pretty extensive media publicity in the past year, particularly in respect to Persian Gulf illnesses. Although we've seen a number of people with legitimate complaints that were Gulf veterans, all individuals who were assessed actually received a diagnosis or at least

fit a -- that could explain their condition.

However, notwithstanding, the Surgeon General has undertaken the following action.

Number one. A letter has been sent under the signature of the Surgeon General to all Gulf War veterans, including those still serving, asking them to -- or encouraging them to come forth if they feel they have any conditions that they believe would be related to their previous service. As well, we have established a 1-800 information line for veterans, and in cooperation with Veterans Affairs Canada, established a register for Gulf War veterans.

The fourth action taken was to establish a special Gulf War Veterans Medical Clinic at National Defense Medical Center in Ottawa.

A medical protocol very similar to your CCEP has been developed and is being initiated at unit level. All assessments will be initiated at unit level; however, those individuals who have inconclusive diagnoses, unexplained illnesses or who remain unhappy with the diagnosis provided or information provided, will be offered assessment at the National Defense Medical Center Clinic.

Prior to leaving on Tuesday, I talked to

the -- the hotline, by the way, was just set up in January and prior to leaving there was 118 calls received over a two week period. Of the 118 -- and there's no studies done in this, but the readout or at least the feel was that about 25 percent were from individuals who had previously been seen for conditions that they thought might be related to the Gulf who had received treatment, but wanted to make sure that nonetheless, their names were going to be placed on this registry.

Another approximately 30 or 40 percent were people who simply wanted to get their name on the registry with no specific complaints. And the remainder were people who felt that they did have problems and that they, for one reason or another, had been missed, hadn't been assessed.

So it's picking up. We don't think -- we have no evidence on any studies we've done at this time that the incidence of any diseases that we've seen show greater incidence in our Gulf War veteran population as opposed to those individuals who didn't serve, but we don't have conclusive studies done in this respect at this point in time.

I'll take any questions, if I can.

Yes, sir.

DR. LEUPKER: How many Canadians were in the Gulf?

CMDR. CLIFFORD: Approximately 4,400, so a very small number.

DR. LEUPKER: So you've got 123 phone calls?

CMDR. CLIFFORD: We had 118. Prior to that we had assessed at least -- we had assessed 12 complete assessments done where the -- this was prior to setting up the hotline or prior to going out with the letter under the Surgeon General's signature. These individuals, we only had 12 that we felt probably would have fit into the similar situation as we've seen here in the States, and virtually every one of those were given a case definition or medi-case definition; a significant number with chronic fatigue syndrome and post-traumatic stress disorder.

But I'm led to believe by the folks that are listening to the phone calls that are coming in at this point in time, a lot of the symptoms coming in are people feeling that they have a condition related to the Gulf. A significant number of them

would appear to be dermatological disorders of some nature.

COL. LEITCH: Dr. Kuller and distinguished ladies and gentlemen, I beg to echo Gordy Clifford's sentiments that I'm pleased to be invited back here again to AFEB and particularly Salt Lake City when skiing is just about perfect, so I'm not going to keep anybody very long, not least because my wife is waiting for me to go and ski somewhere. She's rather hoping, I think, that the insurance policy that she's just got is going to pay off.

(Laughter.)

I'm usually impressed, and always have been, by the American Armed Forces and particularly by the Air Force. I live in awe of those things that roll and bank. What impresses me as well, and mainly it makes me feel just a touch better -- I don't know if any of you have ever worked with the Royal Air Force, but the Royal Air Force works on two principles. One is you buy something brand new and when it's broken you wrap it with masking tape. Now, if anybody's ever seen masking tape it's sort of black. It's like duct tape, only black. And I'm really pleased to see that the American Air Force

has got the same problem.

I shall photograph this before I leave and show it to the Air Force. I was going to say something like "plus ca change" but I know if I do speak in French they will set the CIA on me.

Before I go into details of my report, Mike Parkinson, -- first, a point about PPIP. You should be aware that we stole great chunks of it when we came to the meeting. We're hugely impressed. And it's now floating around -- I think Nottingham University. Dr. McGinnes was asked to lecture there and was an enormous success and we think that that's had one of the biggest spinoffs of all. It's a very impressive document. The whole package is very good and that was a very good study.

David, sadly on of the side effects of what I'm having to do at the moment, one of the spinoffs of what I'm having to do at the moment is that I can't come to the study period in March and I'll tell you why in a second.

I can say something about AIDS prevention, though. Unless you've found something new, we've tried this in the Second World War. It was called bromide. And we found that it was a good excuse

for people to blame the tea, and nobody ever drank it. And I think that's why we took to instant coffee. Bromide doesn't work on prevention of STD either, and particularly in the Air Force.

I've got two subjects. I was determined I would come here and not talk about Desert Storm syndrome. I'm really fed up with it. It's really very boring. But I have to. However, I discovered I've got another subject, as well, and it's suicide, which is just about as depressing, I think.

But before I do, I'll tell you why I didn't turn up this morning. It's because I'm being hounded by an organization called the House of Commons Defense Committee.

Since we last met, I think when the good Senator Reigle left, somebody up there said, okay, we've had enough with the Americans. Let's put somebody on the Brits. And he was sort of reincarnate, only this time it was a lady, and she is the member of Parliament from hell. I'll not name her. I shan't name her. Btu she was at one time, she was Secretary of State for Health and her demise was over salmonella in eggs and some of you will be able to -- yeah. You'll find out who she

is.

VOICE: Yes. Off with her head.

COL. LEITCH: Well, since she's stopped doing that, since she went to the back benches, -- I hesitate. She's a very attractive lady, very attractive, and she has written a book about Parliamentary life and it's -- we would describe it as a bodice ripper. And so this lady does not name names, because she wouldn't do it, but people know who's being referred to in this book and she's become an enormously powerful back bencher.

And so as a consequence, she's picked up Desert Storm syndrome and she is going to make a name for her in it, and so we're all demur to this lady and she's making my life misery by telemedicine, I think it is. It's awful.

Anyway, they're coming out -- the House of Commons Defense Committee is coming out the week of the 6th to the 10th. I'm not sure she's going to come with them and I rather hope not. But if you know anything about the House of Commons Defense Committee -- and you shouldn't. It's about like the Senate Armed Forces Committee, only decidedly more pompous.

I can tell you a little story about them. It concerns our attitude towards pomp and ceremony in that one day there were a bunch of American tourists being shown around the houses of Parliament, and they were a little in awe of it because it's usually old and so on and forth. And coming towards them, all of a sudden passing them came this short gentleman with thinning red hair and he hurried past them, something like that, and kept on going. And at that point coming towards them -- and they were in hushed tones -- was this giant of a man who it turns out -- they didn't know this -- was the Lord Provincial, Quentin Hogg. And he is -- or used to be -- about 6 foot 6. And he went everywhere in these great ermine robes.

The man he'd seen was the leader of the opposition, Neal Kennick, and just as they got in front of him like that, he suddenly shouted, "Neal," and they all dropped to their knees.

(Laughter.)

Which is a measure, I think, of British pomposity.

(Laughter.)

Over the last -- I've mentioned to the

House of Commons Defense Committee and Desert Storm syndrome and you've heard a little of what Gordy had to say. And when I first came here and spoke to you, I told you that we were in great danger of when America sneezes, we catch a cold. Well, we've all got our handkerchiefs out at the moment.

I brought this. It's called a Q&A brief on the Gulf War syndrome, because we've now decided to call it Gulf War Syndrome. And I won't bore you with it at this stage. I only brought one copy, despite what Jean said, mainly because it was a choice of 50 copies of these or my skis and you knew who was going to win.

(Laughter.)

I consider this probably to be one of the most definitive documents the Brits have produced so far on Desert Storm Syndrome, in that it is up-to-date to the end of January. In fact, I think early February. And it shows just how far we've got. And it's answered or posed the questions that you as the Secretary of State for Defense or whatever, might get asked by some hood from the Today newspaper or even worse, the Sun.

I'm not going to bore you by reading them

all out because I don't have time and it's very hot anyway, but it does give a fair picture of the sort of questions we have asked or expect to be asked, and the answers that we have given or intend to give.

As a matter of interest for the statisticians amongst you, so far we have had out of the 44,000-ish -- notice I use the word "ish" advisedly because it's far enough away from the Gulf War now for me to tell you that we never knew exactly how many people we had in theater. We only knew afterwards because those who collected a medal said, "I was there," and they got a medal for being there. And that's because, you know, oh, there's a war. Let's go and join it. And people fell off the plane, as I've told you before, and said, "Guess what I'm doing here?"

So, 44,000. And within that 44,000 we count that was the land forces, air land forces, not those at sea. Of those 44,000-ish, I do want to make sure of active and reserve. We have so far had 208 who have actually registered and come forward saying they want medical examination. Of those 218, so far we have examined as of the 8th of February --

a lot of 8's in this -- we have examined 80 and we have found not one of the 80 suffering from any disease that could not be diagnosed and was diagnosed then and there.

We've had 34 failed to turn up completely. We've had a considerable number more than that, some 400, pushing 500, who have registered with a number of lawyers and pressure groups and they are the people that tend to provide the public image, the public face of Desert Storm Syndrome, Gulf War Syndrome in the U.K.

And it's not up to me to make comment about them, and I'll give you the copy of the paper and you can draw what conclusions you want from the Q&A's here, but for instance -- I will anyway, because I'm -- I will tell you. Here's an example of the sort of people, and I won't give you a name, but a civilian medical practitioner from RAF Stafford would not come forward, was never seen, was never assessed. And that's how we've put them in column.

The star of Channel 4's television program, "Critical Eye," 13th of October 1994, had a cure in the U.S. involving six weeks of intravenous

antibiotics. Never left the U.K. during the Gulf War. And we have columns of these people. We have not got anybody saying, "Would you like to treat my camel," but no doubt it will happen before long.

I promised you I wouldn't go into the details of it, but how many individuals in the MOD are currently involved in examining British government meanness compared to the U.S. governmental compensation? Were all chemicals, NAPS, et cetera, countermeasures, fully tested? Were all vaccines administered on the basis of informed voluntary consent? What about servicemen who say they were not allowed to exercise informed consent in the Gulf? Were compulsory vaccination parades in the Gulf compatible with informed consent? Why were so many vaccines given in such a short time? Were the same medical protective measures adopted by the U.K. as used by our allies? What are the known side effects?

And it runs the whole gamut, including families, deformities amongst children thereafter and so on. So, I'm going to hopefully prevail on Jean to run this off and I give it to you on the understanding that you would use it as scientists,

as opposed to giving it to People magazine or something. Maybe do both. Go ahead.

So, that is Desert Storm Syndrome at this stage. We are, I think -- I am less happy than I was because I see almost the inevitability of public and political pressure overwhelming science here, and it's a great shame. And you'll see from a number of the questions and answers there that my peers and contemporaries in the U.K. feel very much the same way. And there is a need here to be less ambivalent than we've been in the past, but I'm preaching to the converted.

I leave that. Before I go on to talk about for a couple of seconds about suicide, I'll tell you that the good Dr. Ascher only invites me here so I can bring him up to date on the sex life of the Royal family. I'm not able to do that today because I've been forbidden from doing so. But I'll tell you about somebody a little closer to home, and in fact, I can talk about him now because he's dead, poor man.

And he was at one time Foreign Secretary, the same as you have. He was Foreign Secretary and his name was George Brown. And he was a very

distinguished man, a great career diplomatic who people loved and a great raconteur and wit. He did have a slight problem and it was called alcohol.

Anyway, at this particular time in history, he was doing a tour of the South Americas and if it was Tuesday, it was Brazil. It was that sort of tour. And it was one evening at a very large state function somewhere in one of the Central American capitals, and he'd had a bottle of gin or thereabouts. Certainly a heck of a lot. And he stood there looking at the audience and he's obviously getting bored and slightly fractious.

And the band started to play, so he looked around the room and there was an apparition dressed in a long flowing ground. He instantly thought, "Umm." So, he staggered across and he said, "Madam, would you like to waltz?" And the voice came back, "No, thank you, sir, I would not." "Oh, come on, madam. Surely you'd like to waltz. Why not?" And the voice said, "There are three reasons why I don't want to waltz with you. Firstly, you've had far too much to drink. Secondly, this is not a waltz. It's the Peruvian National Anthem. And the third, I'm not a madam, I'm the Lord Bishop of Lima."

(Laughter.)

I told you that we'd been involved and I'm sure this audience will know that there was some concern during the deployment to Haiti that there was an incidence, some sort of link between suicide and deployment and there was a lot of fuss and a lot of energy created, particularly in the Pentagon. I was co-opted onto Dave Suttle's committee just to look at the whole subject.

And we then spent a great deal of time looking at our own information and our own statistics and results regarding suicide in the British Army and the tempo of operations, because that was the question that was asked by General Sullivan. Was there some sort of correlation between the tempo of operations and operations other than war, and particularly the 10th Mountain Division and suicide.

I can tell you unequivocally that the British Army's experiences after 25 years in Northern Ireland and a lot of other things as well, that there is no correlation between suicide and the tempo of operations. Suicides have remained as a constant figure throughout the British Army over the

25 years that we've studied it.

However, where there does seem to be some correlation is between marital disharmony and the sort of whole gamut of social disruption and the tempo of operations and we've long since recognized that. And that seems to be the conclusion that we have reached. That if you keep -- and it's a blinding glimpse of the obviously really. That if you keep sending troops away on short tours, when they come back they have to almost reform their family structures again and the family restructures around and they go away, they come back. And it would appear that nothing changes. That every time you do it it doesn't get any better.

And that's the state that we've reached at the moment. It makes, I think, for an interesting subject for study in the future because there's no question that as the armed forces downsize and these sort of operations increase and the American Army, Navy and Air Force find themselves on these short tours increasingly, then they may very well find that they have the same sort of problem that we have.

Ladies and gentlemen, that's all I've got

to say. And I know it's getting late and I've ran on a bit. I have promised that tomorrow -- I promised Mike that I would speak for a little while about Rwanda and Mike Parkinson heard the presentation a couple of weeks ago.

I've got one small problem. My entire box of slides and the whole bit that goes with it is in either Data Post or Fed Ex on its way to Jean at the moment. If it doesn't arrive by tomorrow morning, I'm not sure that my childhood experience in making those shadow puppets extends itself to a thousand dead Rwandans in the ground or something. So I may have to ask you to extend your imagination, but certainly that's how we stand at the moment on Rwanda.

That's all I have to say.

Yes?

DR. ASCHER: Let me comment for the record on one further aspect of the Gulf War Syndrome issue which I made a cryptic reference to. And I'd like to distribute to the group a newsletter called "Persian Gulf Review," from the Veterans Administration. It highlights one aspect of this which many of you heard me say more than once. And

I apologize, but I'll say it once more.

That for the reservists that were heavily impacted, the only access to care for an illness associated with service in the Persian Gulf, because they are not on active duty and have no health benefits, is to access the Veterans Administration disability system. And it is absolutely clearly stated in this booklet.

Persian Gulf veterans who believe they have health problems that may be related to their military service who have not filed a claim for disability compensation are encouraged to contact their nearest VA.

So, the structural problem I refer to in the system is that there is no way for the people who have the major complaints, a lot of the reservists, to get anything other than becoming part of this system, which is now 14 centers and X million dollars and it is an amazing system.

So that is the structural problem I referred to and I'll send this around for everyone to look at. I received this as a reservist. And it makes statements, such as these syndromes are -- dot, dot, dot -- they believed to be the result of

exposure to environmental factors. So it makes a lot of it fairly clear that it's the party line. So, look it over.

COL. LEITCH: Thank you.

DR. KULLER: We'll take a break now for about 15 minutes and get back at 3:30. We're running a little bit behind so we'll go to dinner a little late, but we're doing all right. Let's walk outside and warm up.

(Whereupon, a recess was taken.)

DR. KULLER: Could we get started? First of all, we're moving our dinner plans to 7:30, so we'll eat dinner at 7:30 so that people can relax a little bit. It's not that far away, the restaurant. I have the directions here and it's about five minutes or so, 10 minutes.

So we'll meet maybe at 7:00 o'clock instead of 6:00 o'clock and give everybody a chance to relax for a few minutes. We're running way behind but we have a lot to do yet this afternoon and I'd say we're about an hour behind, but that's not unusual.

We're going to move on now to look at the hepatitis issue and I think all of you saw the little -- hopefully saw the announcement that the

FDA had approved the use of the new hepatitis vaccine, hepatitis A vaccine, so this is a very fitting time to talk about hepatitis A vaccine.

And Colonel Kelley is going to --

DR. ASCHER: Lew, this is a formal question. We're going to attempt to close on this at the end of the meeting tomorrow with a formal response.

DR. KULLER: Right.

DR. ASCHER: We'll be working on this this evening, the subcommittee, Disease Control. And I'm going to ask Marty Wolfe to lead the discussion in terms of -- as we carry on.

DR. KULLER: There's something in our packet, too, I think, isn't there?

DR. ASCHER: Yes. Definitely.

DR. POLAND: Did you see the Disease Control Subcommittee will meet?

DR. ASCHER: Yes.

DR. POLAND: What time and where?

DR. ASCHER: Well, after dinner whoever is interested, we'll just get together and start working. We'll have it available first thing tomorrow printed to send around for comments,

assembling it at the end of the meeting.

COL. BANCROFT: First of all, I want to bring my greetings from General Zajtchuk who is Commander of the U.S. Army Medical Research and Material Command. February 22nd has been a national holiday in the past, Washington's Birthday. I think there are people back at Walter Reed Army Institute of Research today who are going to remember that with a warm place in their heart as the day that the hepatitis A vaccine was awarded a license by the FDA. I think that's marvelous.

Hepatitis, viral hepatitis, is a readiness issue for the military. It should always be thought of that way. And I'd like to demonstrate a few points about this with some old slides.

This is based on the experience of American Army personnel who had serologic evidence of hepatitis A. Acute disease occurred with symptoms in somewhere between 76 to 97 percent in four different episodes that were studied and the symptoms, of course, are classical for acute hepatitis. But typically, though, the message here is that if they get infected, if soldiers get infected, they get sick. And this was the

experience of hepatitis in Vietnam.

Of course, during those years we didn't have serologic assays for hepatitis A and B and this represents a combined experience that was accumulated after the war, but a lot of this would be A, some of it is B. And this slide is to illustrate the impact of acute hepatitis.

It doesn't kill soldiers. It does make most of them sick when they're infected. And when they get sick, during the Vietnam period in 1966, the average lost duty time was 49 days. In 1970 it had only been reduced to 35 days. And a more recent study, a much more recent study done in the state of Washington which has been reviewed by CDC, the lost duty time is about 27 days in patients from that state.

Consequently, when people get sick with hepatitis A, they lose as much useful work time as the incubation period of the disease. And this is to summarize some studies that were done over the past several years at WRAIR on different Army units, showing the prevalence of the antibody to hepatitis A. And it has run in the 20's in most instance of the active duty force, but by 1989, the Army

recruits shown at the bottom at Fort Campbell, over 1,700 were tested. And the numbers there refer to the numbers that were tested, not the number positive. Only 8.9 percent of them were seropositive for hepatitis A.

And so the message I get from this is that there may be a waning of antibody prevalence levels in this country in our soldiers. The recruits coming in are highly susceptible to this infection, and so we need to have improved ways of protecting them.

Hepatitis A remains a worldwide disease problem. In the United States it's intermediate in its -- the lowest rates of infection occur in Scandinavia, but most of the world has higher transmission of hepatitis A than the United States. But this is a dynamic situation. It's changing all the time as sanitation improves, as food preparation improves.

And when I was assigned to Thailand back in the '70s, we had no instances of acute outbreaks of hepatitis A in the Thai population. The children are all immune or infected, and the adults were all immune. But in subsequent years there have been

outbreaks of hepatitis A in the Thai soldiers. And the largest epidemic on record occurred in Shanghai, China in the 1980's wherein over I believe 300,000 people were considered to be infected, and a lot of them were adults. So, this is a dynamic situation with a virus that's still out there.

Now, a few years ago, Ted Woodward spoke to the AFEB and made the comment that a little history doesn't hurt anyone, so I would just like to make a comment here about hepatitis A research.

Dr. Finestone and his associates discovered the virus in 1973. The Walter Reed Army Institute of Research got interested in initiating studies on hepatitis A in 1976. In 1978, Provost and Hilleman at Merck, Sharp and Dohme showed they could cultivate the virus in cell culture and they also showed that infected marmoset liver could be used to extract virus, inactivated hormone, and then used to protect other marmosets from challenge. And this was the first indication that inactivated virus could be used for active immunization.

We got interested in developing a vaccine as studies showed that you could quantify the infectivity in cell culture. The virus could be

grown in MRC cells which are susceptible for vaccine preparation for humans. Neutralization tests came with Stan Leonard's work and finally the observation of the South American owl monkey could be used as a suitable finite model of hepatitis A disease, and subsequently in testing vaccines.

And this led to this prototype vaccine which was prepared in MRC cells. It was partially purified in activated form. It did not have an adjuvant and preparation was used to immunize all monkeys and then challenged, and was shown to be highly protective in three doses given once month apart.

Subsequently in 1986, eight people received this vaccine in three doses, had very little immune response. But then when given a booster dose at six to eight months, had a sharp rise in serum antibody to hepatitis A. And this was the first demonstration that inactivated hepatitis A virus could be use to immunize people.

Subsequently, the Army developed cooperative research and development agreement with both Merck, Sharp and Dohme and SmithKline Beecham, for testing and evaluating hepatitis A vaccine and

there have been a number of studies, Phase I and Phase II studies of both the products and a large Phase III study of 40,000 children in Thailand of the SmithKline product, which have demonstrated that these products are safe immunogenic and effective.

And with that, I'd like to introduce Major Scott Stanek, who is going to give us some information on a cost benefit analysis which was made of this. The Board has questions from Dr. Joseph, and one of his questions deals with cost benefit analysis.

He will be followed by Dr. David Nalin and then Dr. David Krause, representing the vaccine companies. Then I'd like to clean up at the end with some comments about Dr. Joseph's questions.

MAJ. STANEK: Thank you, Colonel Bancroft.

As a general medical officer at Fort Knox, I frequently saw recommendations from the AFEB regarding immunization policy. I never at that time expected that I was going to be addressing the AFEB. I feel honored to be here today to speak about this subject that so many people have spent time doing research on in the Department of Defense.

My presentation today is on the medical and

military and economic issues in preventing hepatitis A, using a comparison of immune globulin and hepatitis A vaccine.

Historically, hepatitis A has compromised readiness and military operations and therefore must be prevented. The magnitude of the hepatitis A threat on a given deployment is a complex and somewhat subjective judgment. Immune globulin is not an ideal mode for hepatitis A prevention, though in conjunction with its use, the instance has been low on recent deployments. Though more costly, the hepatitis A vaccine mitigates some of the disadvantages of preventing hepatitis A through the use of immune globulin.

The objectives of this presentation are to compare the medical, military and economic aspects of immune globulin versus vaccine for preventing hepatitis A, and to offer possible approaches for the future hepatitis A prevention.

The size of the total force is an important consideration for Department of Defense immunization policies. The active duty component at the end of fiscal year 1993 was approximately 1.7 million personnel, and the reserve component had another 1.8

million personnel. These numbers have decreased with the drawdown as demonstrated by the decreased number of accessions or new service members in fiscal year 1994. The active component strength at the end of fiscal year 1994 was approximately 1.6 million.

This slide indicates where most active duty Department of Defense personnel were serving at the end of fiscal year '93. CONUS, the first line, refers to the United States, and SWA means Southwest Asia. Most were in areas where immune globulin is not required because the risk of hepatitis A is considered low.

Recent deployment, however, to areas such as Southwest Asia, Somalia and Haiti, have placed large numbers of Department of Defense personnel at risk. In 1990 to 1991 the Army alone send 346,000 to Operation Desert Shield and Desert Storm; 144,000 of which were in the area for more than six months.

Not all individuals require immune globulin or vaccine for protection from hepatitis A. This slide shows the hepatitis A antibody prevalence in active duty soldiers and applicants to military service. Using this information, it would be

possible to calculate the estimated number of individuals who have immunity to hepatitis A.

The antibody prevalence curves are similar and prevalence increases with age in both groups. However, acute hepatitis A is rare among active duty personnel.

This slide shows advantages and disadvantages of immune globulin. The primary advantage of it is it's low cost, $5 for five months worth of coverage or $2.24 for two months of coverage. This can also be given in single dose. There's also possible or theoretical coverage against other diseases and the immune globulin provides relatively immediate immunity.

Disadvantages include a shorter duration of protection, difficulty in repeat administration in the field, such as the need to maintain refrigerators. It is also uncomfortable and therefore less acceptable to soldiers.

There is limited protection between deployments and theoretically it may be less safe than the vaccine because it is a human product. It also requires time in the deployment process and also stockpile issues and the uncertainty of future

supplies must be considered. The efficacy of immune globulin is also lower than the vaccine.

This slide shows various studies on the efficacy of immune globulin. In these studies, the efficacies range from 69 to 91 percent. The variability of these studies may be due to the different doses of immune globulin used, the temporal relationship to the hepatitis exposure, as well as the duration of follow-up studies.

Immune globulin usage varies from year to year. This slide shows Army and Department of Defense IG usage from 1990 to 1994. A total of 936,000 miles of immune globulin were purchased by DOD during the time period, at a cost of approximately $10.5 million. This quantity of immune globulin would provide between 2 [million] and 5 million doses, depending upon how it is administered.

The median cost was $2 million. However, this slide includes 1990 during which Operation Desert Shield occurred, and a larger than normal amount of immune globulin was used. If 1990 is excluded, the median cost was $1.5 million.

This slide shows the advantages and

disadvantages of using vaccine. The advantage of the vaccine is that it has a longer term protection and protects during and between deployments. It also has higher efficacy and convenient scheduling before deployment. It also avoids potential national shortages of immune globulin. There is also less discomfort and therefore more acceptable to soldiers.

Disadvantages include its two dose series which requires the soldier to come back. Additionally, the cost. It is more expensive than immune globulin. And finally, it offers single agent protection, namely against only hepatitis A.

This slide compares the direct cost of immune globulin and vaccine for various lengths of time in the area of hepatitis exposure, using an estimated cost of vaccine of $40. The total cost of immune globulin increases with the number of deployments, regardless of whether a 2 mil or a 5 mil dose of immune globulin is used.

The duration of a military career shown in the left-hand column is to illustrate the possible career patterns. Most service members fall into the first group and leave after one tour of duty, either

three or four years.

In fiscal year 1993, 58 percent of the Army soldiers, first-term soldiers, did not reenlist. This was also true for 47 percent of the Navy, 39 percent of the Air Force and 85 percent of the Marine Corps. Individuals who have longer military careers are more likely to have more deployments to areas where immune globulin is required.

This slide estimates start-up immunization costs based on various vaccine costs as applied to different Department of Defense populations shown in the column on the left. Total active duty Department of Defense population at the end of fiscal year '94 was approximately 1.6 million personnel. Active duty forces are defined as the Army's 18th Airborne Corps, the Marine's Fleet Marine Corps, the Navy's Seebees or the construction battalions, and Air Force Air Combat and Mobility Commands.

Special Forces include special operations units of all three services and accessions refers to new service members entering active duty for the first time.

For a total force, the start-up cost would

range between $48 million and $96 million, depending upon the cost of the vaccine used. This cost would be doubled if reserve component personnel were immunized. Alert Force start-up cost would range from $12 [million] to $24 million. Accession costs of $11 [million] to $22 million would be recurrent annual cost. A recurrent annual cost would also result from turnover in the Alert Forces and Special Forces.

For the Army's 18th Airborne Corps, units within the Corps have an average turnover between 8 and 10 percent.

As indicated previously, some individuals already have immunity to hepatitis A. If this sero prevalence information is applied to different populations, the results shown are obtained. The total Department of Defense cost would then range from $39 to $77 million and Alert Force costs would range from $9.6 to $19.2 million. Decreases in cost are less for the Special Forces and Alert Forces. However, the cost of performing screening tests is not included in the numbers shown. An attempt to estimate these screening tests, as shown on the next slide.

In this slide, the various costs of the first screening test are applied to the same populations shown on the two previous slides. The cost of screening the total Department of Defense active component ranges from $9.7 million if the cost is $6 per test, to $19 million if the cost is $12 per test. For this population, the cost of screening plus vaccination of non-immune equals the cost of vaccinating all personnel if the vaccine costs $60 and the screening cost is $12. There is no cost saved by screening the smaller population shown.

Based on past experience with large contracts, such as contracts for HIV screening, it may be possible to obtain a screening test for lest cost than the cost shown here.

Medically, the hepatitis A vaccine is safe, well accepted and provides long-term protection with superior efficacy compared to immune globulin. Militarily, hepatitis A vaccine enhances readiness, however, the use of immune globulin in Operations Desert Shield and Desert Storm, Somalia and Haiti has been associated with no militarily significant increase in hepatitis A.

Economically, the vaccine is much more expensive than immune globulin and its longer duration of protection is mitigated by the short military careers of most service members.

Hepatitis A vaccine is probably indicated for food service workers and Special Forces personnel. The indication for food service workers is because of the potential for causing an outbreak within one unit.

Hepatitis A vaccine administration for the entire force or all accessions is probably not the best use of limited resources.

Finally, hepatitis A vaccine may be indicated for segments of Alert Forces, such as careerists, and this approach deserve further economic analysis based on a detailed study of personnel retention patterns, as well as deployment frequencies.

Possible recommendations for the use of the vaccine are to have the vaccine given on a routine basis only to food service workers and individuals assigned to Special Forces and those members of the Alert Forces who are anticipated to deploy frequently to areas of high risk.

Immunizations of other members of the Alert Forces be considered based on mission requirements, such as the deployment sequence.

And finally, hepatitis A vaccine be given to other active duty personnel and non-active duty beneficiaries in accordance with the recommendations of the Advisory Committee on Immunization Practices.

This concludes my presentation. Do you have any questions?

DR. POLAND: Have you actually found any outbreaks of hepatitis A due to food service workers in the military or who work with the military?

MAJ. STANEK: There have been case. The one that comes immediately to my mind is an outbreak which occurred in a field training exercise in Washington state in 1989, I believe. And that's a recent outbreak, relatively, compared to the outbreaks of hepatitis in the past.

DR. KULLER: The model that you presented depends to a considerable degree, it seems to me, on what's going to happen in civilian population with regards to recommendations. And I think that's a very critical variable because it seems to me that if the recommendations in the civilian segment were

to immunize everybody, although you could say the cost is coming from the Department of Defense, in reality one would have a rather strange argument that one wouldn't immunize everybody in the military, even though the recommendation was that you immunized everybody because you'd have to wait until they left the military to get immunized.

I mean, you could say that, but in reality it would be open for derision and, I would think, strange scientific logic.

On the other hands, the recommendations not to immunize the U.S. civilian population, then your modeling is probably very interesting, although I would also question the argument about food handlers, unless one had some solid data that that was contributing substantially to epidemics within the military.

MAJ. STANEK: I realize I only mentioned the food handlers right at the end of the discussion, and that is mainly a focus put in with a perspective from the readiness issue. If everybody leaves here tonight and goes and has dinner someplace and contracts hepatitis A and then they go back all over the country, it will not -- it

potentially would not have the same impact as everyone going to one dining facility in one unit in a combat situation and all of them getting sick in that area.

So it's included as a readiness perspective.

DR. BROOME: And there's such a history of food outbreaks in civilian. Why shouldn't it happen in the military setting?

DR. STEVENS: But the interesting thing is I think -- I don't know that the ACIP has come out with its recommendations as yet, but I've seen a draft of it and I'm pretty sure that food handlers are not part of the ACIP recommendations, despite the -- that was a question I asked them a month or so ago.

COL. BANCROFT: Yes. They downplayed it.

DR. STEVENS: Yes.

COL. BANCROFT: But the problem is when a food handler is suspected, --

DR. STEVENS: I'm not arguing really against that, per se.

COL. BANCROFT: -- when an outbreak is associated with a dining facility, that's when you

draw down the IG supply and it happens all the time basically. And if we can avoid having those incidences in the military, we have an opportunity to do that.

DR. STEVENS: There's another kind of an issue in a sense. And I think one of the points you made is an interesting one about the problem with immune globulin depleting. I mean, that the immune globulin is being depleted for the country. I think that in fact happened with your deployment to Haiti.

COL. BANCROFT: It happened during Operation Desert Shield.

LT. COL. KELLEY: And it still is happening. It's happening right now.

DR. STEVENS: I mean, that's what I mean. It's still happening with the Haitian deployment.

COL. BANCROFT: Either due to the Haitian deployment or due to the new requirement -- it was the sequence of deployments. Operation Desert Shield exhausted the national supply and we had to start buying it from Italy. Rwanda depleted some. And then Somalia depleted some and Haiti most recently. And at the same time we're continuing to operate in the civilian community which we're also

pulling down. And Hal Margolis and I had a number of discussion about how we were going to -- how we chucked it in. But the vaccine will relieve this sort of thing in the future.

And the estimates of the cost of the IG that Scott presented here and the current costs, the cost of IG may be substantially higher -- if the FDA puts more restrictions on the approval of lots.

DR. WOLFE: Talking about costs, both for the vaccine and the screening, since the vaccine has been released, I think it will be essential for us on the Board -- we're going to discuss this -- for Dr. Krause or somebody to tell us what it's going to cost the military for the vaccine as of today. It's sort of glossed over and I think we would like to have some commitment as to whether it's going to be $50 a series, $60 a series or what, because that's going to be very important in how we define the cost effectiveness.

Secondly, in terms of your screening tests, I would question the cost of $12 a test. From personal experience, we have a program at the State Department. I've also initiated a program at the World Bank of pre-screening because we think it's

cost effective in those populations, in those adult populations. Getting the materials and leasing a machine from Abbott, it costs somewhere about $3.50 to do the hepatitis A test and I think you should for -- if you're going to do it, shoot for a goal of something like that, not to farm it out to some contractor who's going to charge you $10 or $12 a dose.

And that, again, is going to be very essential what that test is going to cost, as to how we're going to determine whether pre-screening is going to be cost effective at certain age groups, probably above age 25 or 30, I would think, not at age 18.

MAJ. STANEK: That's right.

DR. WOLFE: So if we can get something on that or you can start thinking about doing some more investigations of the cost of the test and various options that you might have, one of which is to do it in-house somewhere by leasing the materials from Abbott, which might be considerably cheaper.

DR. ASCHER: As he said, you could add it to HIV, which is already in place.

DR. WOLFE: Exactly. That's what we're

doing. HIV, hepatitis B, hepatitis C, HTLV and hepatitis A all on one machine, all on one specimen.

DR. ASCHER: What I'm saying is they already have a serum bank of all the samples. You could go do the entire active force right now on retrospective samples. You could add this to the next round of HIV screening for $1.00 or $2.00. That's what HIV costs. You don't have to pay for the sample. So the numbers are way too high.

COL. BANCROFT: Is there a question back there?

LT. CDR. ARDAY: Just a comment. You commented about the cost of doing -- we're looking at strictly direct costs here. I mean, we haven't factored in the indirect cost. When you start talking about these different options here and how you're going to do it, if DOD does it in-house, then there's going to be more indirect costs associated with that than if we go over to a contractor and it's just included in the price.

LT. COL. PARKINSON: What is the FDA licensure status as far as the duration of protection? I hear you say five years, --

COL. BANCROFT: Let's wait for this next report and then --

LT. COL. PARKINSON: I'm sorry. The only point to make concerning this is that we'd look at the -- I mean, the numbers that were cited here in terms of 35 percent positive for Army troops at the age of 35 to 40 is what I'm looking at.

DR. WOLFE: That's nationally.

LT. COL. PARKINSON: Is that?

DR. WOLFE: And above age 30, national figures, I believe, are somewhere around 30 percent of the population is already immune.

DR. POLAND: These are equal to or slightly lower than the figures that I've seen, surprisingly.

DR. ASCHER: Right.

DR. STEVENS: But it's also -- getting, as you were suggesting, a kind of a cohort effect. That the younger people --

COL. BANCROFT: We can't tell how much is cohort and how much is new infection. Some is new infection occurring during service.

DR. WOLFE: There might be quite a racial difference, too, between the inner city folks and those that are coming from rural areas. I mean,

even white versus black. I don't know what the national figures are, but I believe they're higher for blacks and Hispanics than for whites.

COL. BANCROFT: I think the point that we want to make here, though, is that we are protecting our soldiers during deployment. We don't see disease then because they get immune globulin. But when they come back home and during the period between deployments we have outbreaks. We've had epidemics associated with child care centers. We've had food-borne outbreaks in the past. We've had other -- and that's probably much of our attention is occurring between deployments.

DR. GWALTNEY: What's the shortest interval in which the booster can be given?

COL. BANCROFT: Let's let the manufacturers describe their product.

DR. KULLER: Can we go back again? I'm still confused. Somebody must have some idea about what the recommendations are going to be on the civilian segment.

DR. STEVENS: I don't think -- my understanding is it's not going to be universal immunization at this point. It's going to be

targeted. DR. ASCHER: There's a problem that the formulation is, I believe, not approved for less than 18.

DR. WOLFE: 18.

DR. ASCHER: And one of the target groups, at least in our epidemics, is the pre-teens where it really does run wild. And so there are trials right now. I don't know what stage they're at, but there are trials in California doing the pre-teens in our highest counties. So once they finish that package, they might submit that modification, which would then give a coherent policy. But probably now this will be constrained by the 18 limitation. You can correct me if I'm wrong.

COL. BANCROFT: Why don't we go ahead and have the presentations by the companies and we can get into a discussion of some of these points.

Dr. Nalin?

DR. NALIN: Distinguished colleagues, ladies and gentlemen. I will be describing the experience with the Merck purified inactivated hepatitis A vaccine, VAQTA, V-A-Q-T-A, for which we expect licensure within calendar year 1995, as previously announced through official company

sources.

The key thing that I want to leave with you after this presentation is that the one cardinal difference between the Merck vaccine and other vaccines is its purity. By our calculations, based on antigen to protein ratios, the Merck vaccine is 80-fold purer than other hepatitis A vaccines.

Now, what are these impurities? Basically, they're chiefly MRC-5 cell products, since the virus is grown in MRC-5 cells. And while these are used in many vaccines, when adjusted, they are known, as with the publications by Quinnen dealing with the rabies vaccine, to cause IG mediated allergic reactions.

And so we spent a year and a half developing the most refined purification methods to remove them and the vaccine has no detectable protein, except the hepatitis A viral protein antigen. And therefore, we can express the amount dose as 25 nanograms of viral protein based on amino acid analysis of the product on silver -- and there's no other protein detectable by any other standard methods.

The other factor we'll go into is that this

is the only vaccine which has in a field trial demonstrated 100 percent protection starting day 21 after a single intramuscular dose. That dose also induces immune memory. And I'll show the effects of use of the vaccine in a single dose up to 18 months and then in a booster up to 3-1/2 years so far studied in the Monroe field trial area, to essentially stop interruption of the disease for to date almost four years in a previously heavily affected area.

The strategy of the vaccine was based chiefly on two observations. One is the well-known rapid-passive immunity conferred by immune globulin associated with passively acquired neutralizing antibody. And the second is the long-term protective immunity that was shown years ago by Villarejos in his study published in the American Journal of Epidemiology, that in a field outbreak situation, individuals who had grown up in an endemic area now free of hepatitis A relatively speaking whose titers had waned to undetectable levels and who were then case contacts, had no disease but were shown to have an anamnestic reaction with no detectible IgM but a huge rise in

IgG.

And so what this means is that long-term immunity depends upon immune memory and does not require persistent antibody.

I'd like to briefly discuss the safety record of VAQTA to date.

Out of more than 8,400 vaccines, about half of them children, half adults, we have had not a single serious vaccine related AE to date. As far as adverse reactions, in placebo controlled trials, including the Monroe trial, the adverse reaction rates have been the same as after placebo and after the booster there were no placebo boosters because for ethical reasons we had to vaccinate the initial booster recipients when the trial ended.

But if one looks at the AE rates after the booster, they're lower than after the vaccine or the placebo when given as the first dose.

I'll briefly discuss immunogenicity. The assessment of antibody response was chiefly by the modified HAVAB test, which is the same as the HAVAB test detects total IgG and IgM, but uses 10 times the amount of serum compared to what the manufacturer recommends and is more sensitive to

pick up low early post-vaccination antibody levels compared to post-convalescent ones.

Various other tests have been used also, including the Varner neutralization test, but I won't go into the technical details because the message I want to leave with you here is that the antibody titers are a game because there's no standardization. Each different test, each manufacturer's test, each other test has a different format, different reagents, different affinities, detects different antibodies.

And if, for example, we put our sera into this test, an individual who registers by modified HAVAB at 10 mIU per mL, a mil international units per mil compared to WHO standard anti-sera, if we put that into a modified EIA, it comes out 20 using the same standard anti-serum.

So, for those of you who follow the literature, you know there are several publications on this and we have to wait for WHO to standardize all these tests before we can assume that one level is truly higher than another. I think the important thing is that each test is validated and within its own cutoff is okay, but I have urged the CDC to

avoid saying that a given level means seroconversion, as with Hep B, because there's no such standardization and that could be highly misleading.

Furthermore, as I'll show you later, even seroreverters who become negative after they had seroconverted, have immune memory and are protected.

Now, here are the overall seropositivity and GMT rates in VAQTA recipients 2 to 17 years of age here; 18 to 70 years of age here. The doses we are recommending, 25 units or 25 nanograms and a half an mL for this age group, and 50 units in 1 mL for this age group.

Notice that with these levels we achieve by week four 97 percent seroconversion of previously seronegative individuals, with a GMT of 43, our cutoff being 10. And 95 percent in the older individuals of all ages and weights we increase this dose because at this dose level, older and heavier individuals had lower seroconversion rates by week four and we wanted to achieve rapid rates for travelers and military and so on.

This is the GMT in the older individuals. At week 24, basically the results are quite similar,

slightly higher GMT's. At that point a booster is given. This is a two-dose regimen for children and for adults. And then one sees a rapid anamnestic response with very high titers which in ongoing studies have persisted for three years in most individuals.

This illustrates the overall 25 unit first dose experience. This is four weeks after the first dose and with the consistency lots. And then after the booster, a 49-fold rise in the younger age group. And in the older individuals, as expected, a lower fold rise. But nevertheless, in both groups a clear anamnestic response to the second dose.

Now, this is in cohorts -- not cohorts, but subgroups of the Monroe study in children 2 to 17 years of age. They were divided after we showed efficacy of one dose into three booster groups. The first got the booster at six months, the second at 12 months, and then down here 18 months. Notice that the important point here is that whenever they got the booster, whether it was at six months here, 12 months or 18 months, four weeks later they all had a clear anamnestic response with very high titers. There's no statistically significant

difference between these titers.

So at least out to 18 months immune memory was shown to be well preserved and I'll show you a subset of the few who seroreverted and then were boosted to underline this.

These are those children who -- two of them at six months having previously seroconverted based on the one month blood, then seroreverted and were boosted but had an anamnestic response. The same thing for the 0-12 month group. Three individuals in that group seroconverted -- seroreverted, but nevertheless responded to the second dose with anamnestic response. So immune memory was intact.

The same thing is true in the 18 month group if we can see a little bit further over. I'm sorry to cause you trouble there. But out of seroreverters, again, strong anamnestic responses.

So we continue to follow them, and this bodes well, I think for long-term immunity based on the same principle as the record showed; that is, immune memory. And we'll show you the practical effects in the community.

Basically, we can conclude then that seroconversion indicates induction of immune memory.

And since our seroconversion rates are very high at week four, we can expect that most of those individuals have intact immune memory for the period of time, at least as long as we followed them.

I'll go into a little detail on the Monroe Trial design. It was a typical classical randomized placebo-controlled double-blinded study. There was an independent monitoring committee. All the cases were evaluated to see if they met the case definition which was one -- which essentially constitutes significant hepatitis A disease.

The aim of the trial was to attempt to show protection after the first dose. Fortunately, the epidemic came shortly after the first dose was administered and we were able to do that. And then, as I mentioned earlier, we gave a booster at six, 12 or 18 months to look for signs of immune memory.

The clinical case definition was one or more typical clinical signs or symptoms suggesting hepatitis A, plus a diagnostic HAVAB-M test and a two-fold or greater ALAT elevation. Actually, as you'll see later on, the mean fold ALAT elevation in those cases where after the code was broken, -- who before the code was broken were diagnosed as Hep A,

was 14-fold above the normal limit.

The seroconversion rate was checked in 305 of the children who were in the trial, and this is among vaccinees out of a total of approximately 1,000 vaccinees. There was about an equal number of placebo recipients. And -- I'm sorry. About 500 vaccinees and 500 placebo recipients. And the seroconversion rate at week four was 99 percent with a GMT of 42. Only one of these children had not shown seroconversion; that is, had a titer less than our cutoff of 10 by week four.

The clinical diagnosis of the 44 hepatitis A cases which were judged to have fulfilled the case criteria and the protocol by the committee before unblinding the study are shown here. And as you can see, judging by the diagnostic IgM, the ALT levels, the percent with Icterus or other typical signs and symptoms, and here we used only those who had the clinical history of Icterus, plus a confirmatory bilirubin level. There were a number who had maternal diagnosis of Icterus, but by the time they took the blood we couldn't prove it, and so we discarded them.

So it's fairly -- we were fairly rigorous

about it.

The results of the trial which many of you have read in the New England Journal article showed that based on the initial period of 50 or more days after the injection to avoid confoundation by cases already incubating the disease since the outbreak had started just before the vaccination finished, in this group there were no cases of among vaccinees; 25 among placebo, yielding an efficacy of 100 percent with a very significant P value and an 87.3 one-sided 95 percent confidence interval.

And then if we looked back to day 21 after the single dose, we still had 100 percent protection with high statistical significance.

During the first 18 days, there were a small number of cases in both groups. No statistically significant difference here. We did get one strain from one patient that we could obtain and it was not the vaccine strain. And we have never seen cases in vaccines outside of this situation where there's an active epidemic going on. So, this is due to wildfires.

The conclusion was that we could demonstrate 100 percent protection starting day 21

after a single dose and then in examining the follow-up, we have established that we could eliminate yearly community epidemics over the three years to date since the trial ended.

The trial indicated that the onset of seroconversion at weeks three to four parallels the onset of protection.

Here are the trial result summaries in terms of the number of hepatitis A cases. You see those occurring in vaccinees in yellow up to actually day 18. After that, there was no case until day 21. But after that, all of the cases are in the placebo recipients shown in green. So a very clear and dramatic demonstration of the protective efficacy after one dose.

Now, here we have the annual epidemic records from Dr. Werzberger's practice in Monroe showing that each and every year for the five years preceding the trial and Dr. Perry Ellis tells me that he -- Perry Smith, rather -- that he has data going back even further than this showing annual epidemics. There were significant numbers of cases. There was one year in which the cases dropped following an intensive immune globulin and

handwashing campaign, but there were nevertheless some cases.

So this was a very extensive record of hepatitis A disease.

This is what happened in Monroe. This is the trial period and this is the end of the trial here when we vaccinated the placebo recipients. And these are cases in non-trial participants out of the total. These are the trial cases. And I've shown you that with the exception of the few in the first week, all of them were in the placebo group.

And if we go out here to May of '94, you'll see there have been some sporadic one or two additional cases imported into the Monroe community from the parent community in Williamsburg, Brooklyn, but there have been to date no cases in any vaccinees in the Monroe area. This, in contrast to the annual epidemics that you saw in the previous overhead.

Now, if we look, however, at the adjacent Hasidic communities, the same community as Monroe in the towns within the surrounding several miles, we see that in contrast to Monroe where we were able to eliminate cases in here and -- could we see the

right-hand border here? Yes. -- and had only the four imported cases in 1994, in the neighboring communities of Spring Valley, New Square and Monsey, each year the epidemic has continued as it had in Monroe for the previous five years.

Therefore, it appears that from this and periodic sera surveillance data, that immune memory confers long-term protection from clinical disease in Monroe, just as it did in Costa Rico in the Villarejos study. We are accumulating in these serial bleeds, some individuals -- we now have 10 cases but five immaculately proven cases where during the interval of zero to 18 months after a single dose they were -- a case contact. There was a sibling in the family who was a case or there was somebody who visited who was sick. And we were able to get blood showing a dramatic rise after the case contact without any booster dose.

So, it looks as though the response is very similar to what Villarejos saw.

These are the well-known risk groups as you'll readily recognize and certainly we would recommend it whenever appropriate and cost effective for such individuals as well as consider it for food

handlers who may not be at increased risk themselves, but who are associated with numerous outbreaks that affect the restaurant industry.

The universal pediatric use I think will eventually come when it can be combined into combination vaccines to avoid an extra clinic visit and when the combination vaccine economies will be sufficient to justify the slight additional cost of another antigen.

This has already been covered, the comparison between the protection by IG, the protection afforded by vaccine. In this case, more than 3-1/2 years after the first dose and 18 to 24 months after the second dose, elimination of the disease from this highly exposed population.

Just looking at cost benefit for vaccinating the estimated U.S. birth cohort if it were in a combined pediatric vaccine with 4 million infants, one would about break even since the CDC considers that the annual cost to the U.S., at least as of five years ago, was estimated to be $220 million. So vaccinating the birth cohort at this price would save a little bit in money. Assuming that there hasn't been an increased cost in the last

five years could save a lot if one updated the cost.

But this would bring a benefit of elimination of the disease. And in fact, in collaboration with the CDC, we're testing out the theory of whether Monroe as a module can apply to chronically affected counties like Butte County in California, where we've given them 30,000 doses to vaccinate the children in the current ongoing outbreak there to see if their theory is correct. Namely, that most of the hepatitis A in this country is passed on to older individuals by children with mild or moderate disease.

Recommended military use has also been covered. And I think we essentially agree with everything that's been said there.

Concurrent use. Concurrent use with IG. There are several studies published with the SmithKline vaccine. We have also completed a study. It's under analysis but I can tell you that IgM seroconversion measured by exclusively sensitive techniques for the eight weeks after the initial dose in individuals receiving concurrent IgM VAQTA, show that the individuals, almost all of them do respond at that point to VAQTA. And the week 12 and

beyond bleeds where there is no detectable immune globulin onboard compared to the control groups receiving immune globulin alone or vaccine alone, the preliminary data suggests that there may be a minimal -- as has been shown previously -- a minimal effect on titers but the seroconversion rates are the same and the titers are substantial.

With hepatitis B we plan other trials but have completed so far only the trial at uses where we use the 25 unit dose in young adults with or without recombin vaccine and saw no interference. So we don't anticipate any interference in the ongoing trials of the 50 units.

Pending our studies with all the standard travelers vaccines and those, we have no data on to date but are pursuing it.

Thank you.

COL. BANCROFT: Questions for Dr. Nalin?

DR. STEVENS: Observation of efficacy by the third week is really in one sense sort of startling because it implies that given the incubation period for hepatitis A, that some of those people were protected even though they already may be exposed or exposed very shortly after they

got the first dose of vaccine.

DR. NALIN: Right. I think that's probably true and we are going to look into that in a little bit more mathematical way because we've recently had an experience that -- Dr. Santosham on the Navajo reservation had a study in which he started to vaccinate and then a large local community outbreak came upon him. And we noticed that a lot of the teenagers who have a pretty high clinical case attack rate in that population these days are the ones who are in school, had wild boosts without any symptoms. And we were planning to try and see if we could get the Navajo numbers.

I think both studies together do indicate that, especially considering the data from early studies showing the pediatric incubation period for Hep A is longer than that of adults, it may be as long as 50 days, even if we assume it's slightly longer, say 30 days, that would still suggest that we can protect some individuals already exposed to the disease during the incubation period.

We plan eventually to do a post-exposure prophylaxis study.

DR. STEVENS: That was my name question.

DR. NALIN: And that will be the final way of solving it. There are some communities who have expressed interest, who are highly exposed and who expressed interest in collaborating on such a study in a controlled way. And although it's going to be a little dicey, like leaving a payload of vaccine and hoping the outbreak occurs within the expiring date or something, we hope that eventually we'll be able to look at that.

COL. BANCROFT: Dr. Gwaltney?

DR. GWALTNEY: It's certainly wonderful to see your success with a new vaccine at the time when a lot of vaccines aren't working so well. And you're really to be congratulated.

DR. NALIN: Thank you.

DR. GWALTNEY: In the military, a week might make a difference in deployment. Do you have antibody results two weeks after vaccination?

DR. NALIN: Yes. Here again, there's a little caveat as to what assay one is talking about. But by modified HAVAB at the 1500 dose, we can detect seropositivity in 70 percent by week two. If we use the -- we have not -- the caveat here is Merck has not validated the Boehringer-Ingleheim kit

which is sold in Europe, but our investigators in Europe, using that kit, can detect what they regard by the test criteria as seropositivity in up to 85 percent by week two.

So, if that subsequently is validated and if Cladd's suggestion is correct that even if you get in there slightly after exposure, if that proves true, then early detection will be demonstrative.

COL. BANCROFT: Okay. Thank you.

Dr. Krause for SmithKline.

DR. KRAUSE: Thank you for inviting me here today and thank you, Colonel Bancroft. It's a pleasure to be here and to present the data about our vaccine.

And of course, I guess the thunder has been stolen a little bit because you've heard the news that yesterday the FDA decided to join the rest of the world and license this product, which is presently licensed in 41 other countries. So it was kind of a nice day for me since I've devoted about five years to this. But I must say that we could not have done any of this without the collaboration of the military and the folks at Walter Reed have been excellent partners and it's been a real

pleasure.

So, I just wanted to illustrate my talk with a slide, so I chose this slide for three reasons. Is this in focus? Because I can't tell.

This is General Anthony Wayne from the Revolutionary War. And, of course, hepatitis A has probably always been of military/medical significance in the United States. The second reason I chose this slide was because of the statue's close proximity to my residence. And the third reason is because of it's hue.

There's a quote in General Schwartzkoff's book that says in 1946, turning yellow was just part of the adventure.

(Laughter.)

So you've seen this slide already and I don't need to reiterate this. But it's obvious that many places in the world where hepatitis is highly endemic are of obvious significance to the military.

We've rehashed all of this and I won't rehash this, except to say that the lower efficacy estimate of 73 percent comes from a 12 month study in World War II. So that as one looks further and further away from the dose, the lower the efficacy

gets, not surprisingly.

Well, this is the dosing schedule of HAVRIX, which is now licensed and which will be available for you. For children 2 to 18 years, 360 ELISA units. We've referenced this to an internal standard. The primary series consists of two doses one month apart and a booster dose may be administered anytime between month six and 12.

For adults greater than 18 years, the dose is 1440 ELISA units. It's a single primary dose, then followed by a booster six to 12 months later. And, of course, it's IM in the adults. Again, these are all licensed doses at this time.

Critical development of this product began in December of 1988 following the completion of the CRADA with Walter Reed, and the product license application contained 43 clinical studies. And you see here the number of subjects receiving the various preparations.

In the protective efficacy trial conducted in Thailand by Colonel Innis, which I'll be showing to you, 40,000 children, including crossovers, received the vaccine. Since the vaccine has been licensed for about four years in Europe, we have

distributed many millions of doses.

Now, the initial clinical development for adults was with 720 ELISA units, two doses a month apart. And in fact, this is the dose that is licensed in many European countries, although there are a few countries with 1440, the dose which is licensed here is licensed.

And with this dose, one month after the initial dose, we found a 95 percent seroconversion rate in all comers, with a geometric titer of 305 and a brisk anamnestic response a month later. And virtually everyone seroconverts.

This is a study we did in Fort Lewis with Bob DeFraites and other investigators, and it's a somewhat complicated slide. But in this trial -- and I'm sure this is hard to read -- we gave either two doses of the 720 to the blue group or we gave 720 at days zero and 14 or we gave 720 at zero and 30 days or at zero and 180. And up here we see the seroconversion rates. And these are the geometric mean titers. You have to read this along this axis and the seroconversion rates are over here.

And I recognize this slide is complicated, but I want to bring out one point on this slide.

And that is that the blue group that got 1440 at time zero had a significantly higher -- and this was statistically significant -- higher seroconversion rate at day 15 than the other three groups combined. And this trial, along with several other trials which we conducted in Europe, led us to believe that it was worthwhile to double the antigen content of the vaccine. Not that we got ultimately higher geometric mean antibody titers, but we found in all of these trials about 25 percent faster acquisition of antibodies.

Again, when we studied the 1440 dose, we found at day 15 -- this is in all of the clinical trials -- an 88 percent seropositivity rate two weeks after the initial dose. If one looks instead at neutralizing antibodies at two weeks instead of anti-HAV by ELISA, about 60 to 80 percent of the subjects have neutralizing antibodies, whereas virtually everyone has anti-HAV -- one month after the dose.

These antibodies persist very nicely until month six. When a booster is given, again, one sees an extremely brisk anamnestic response.

So again, we studied three schedules and

720 at zero-one for adults; 1440, a single dose for adults; and 360, zero-one for children. I've not shown the children data but what's remarkable is that after the primary dose how very similar these numbers are, both in terms of both seroconversion and geometric mean antibody titers. So the 1440 has the obvious advantage of achieving this one month earlier.

Again, it doesn't make any difference if we give the booster dose at month six or at month 12. Subject retain anti-HAV very nicely between these two points. There's no difference in the ultimate geometric mean titer obtained. And so the label says that the booster dose can be given any time between month six and 12.

This is a study which started over 40 years ago in which we studied 720 ELISA units on a zero-one-six schedule. Again, you'll note that at month seven, after the primary course plus the booster, you have a geometric mean titer of about 4,000. We then followed these subjects out, and of course, one of the questions that has already been raised at this committee and is commonly raised is how long will protection last. And I guess the ultimate

answer of that is time will tell.

However, we have real time data now to four years -- this slide only goes to three years. But to four years, we have 100 percent seropositivity. It's also interesting to note that a lot of the -- well, since this is a log scale, about 60 percent of the loss occurred between month six and 12, but then there was a dramatic decrease in the loss of antibody, and this rate is constant at about 14 percent per year.

Now, if this continues, protection could be expected to last between 20 and 30 years. It's also possible that given the incubation period of the virus that protection will actually exceed the persistence of antibodies. So I think that we can feel quite comfortable that the vaccine will provide long-lasting protection.

These are safety data from the three preparations which we've studied in which we solicited a variety of adverse effects, mostly diary records from thousands of subjects. The most common local effects is soreness, not surprisingly, at the injection site. The most common systemic effect was headache. All other local and systemic effects

occurred in less than 10 percent of the recipients. I can tell you that in the military,the percentage of local and systemic effects was much less than in this. In fact, the incidence of headache in the military was about 2 percent.

Now, we did a study in travelers in Germany in which we vaccinated people at 80 travel centers. There were several thousand people in this trial. It wasn't a randomized placebo-controlled trial. It was an open label trial in which people going to endemic areas receive simultaneous immunization or just receive hepatitis A vaccine.

When hepatitis A vaccine was given just by itself, two doses of 720 at zero-one, the geometric mean titer two weeks after the second dose was 500. These are the titers in the recipients who received a simultaneous immunogen. You can see that clearly there's no interference with the anti-HAV response when any of these vaccines are given, although obviously the numbers for IPV are quite small.

We did do one randomized controlled trial with hepatitis B vaccine. Absolutely no difference in the hepatitis B response if hepatitis A is given concurrently. No difference in the hepatitis A

response if hepatitis B is given concurrently.

Well, this is the field trial conducted by Colonel Innis in Thailand. This was a remarkable trial that was published in JAMA last year. The design of this trial was a randomized double-blind trial in which the test vaccine was HAVRIX. The control vaccine was hepatitis B vaccine. The schedule was three doses, zero to 12 months apart. Forty thousand children were randomized and entered into the trial. The children were between ages 1 and 16 years and he used primary schools as the vaccination centers and as the centers for surveillance for hepatitis A.

And there was a crossover at month 18 or at least the trial design called for a crossover if the vaccine was found to be safe and effective.

Children grades K through 5 was the criteria for inclusion, although a couple of younger kids slipped in. The only exclusion criteria was pregnancy and the children weren't screened for anti-HAV.

The case definition was a bit different than the Monroe trial that Dr. Nalin told you about. A two-day school absence triggered a visit by a

school nurse. The nurse then went in and drew blood. She came back two weeks later and drew blood again. ALT's were run on both of these bloods and if there was any elevation of the ALT, any, anti-HAV IgM was run on the paired specimens.

So, to be a case, it required a two-day school absence, any elevation of ATL and a positive anti-HAV IgM on one of the two paired specimens.

This is what happened to cases. The kids were vaccinated in January of 1992. Surveillance did not start until several months later because the kids went on vacation in this interval. So you can see that in the hepatitis A vaccinees, that is the test group, there were two cases of hepatitis A. In the control group which received hepatitis B vaccine, there were 32 cases of hepatitis A.

They continued to follow the children for another six months, during which time cases continued to occur in the hepatitis B recipients but not in the hepatitis A recipients, and then the entire cohort was crossed over to the opposite vaccine.

Now, these two cases were both extremely mild and had ALT elevations less than two times

normal. So if we had used the criteria that were used in the Monroe trial, we would have had 100 percent efficacy. However, according to our case definition, the efficacy was 94 percent and after the 12 month booster dose, the efficacy was 100 percent and the cumulative during the 18 months, the efficacy was 95 percent. There was less than 1 chance in 10,000 that these results would occur by chance.

Now, we also have conducted a project in Alaska with Dr. Brian McMann in order to control a large epidemic of hepatitis A using HAVRIX without the concurrent use of immune globulin. Hepatitis A is a huge problem in Alaska and epidemics occur every five to seven years. This shows the 1988-89 epidemic. Hundreds and hundreds of cases occurred during this epidemic.

There was another hepatitis A epidemic in 1992 and '93 in interior and northwest Alaska. There were over 500 cases of Icterus during this epidemic and they mostly occurred in adolescents. There were seven fulminant cases and four deaths.

So, participants in this open label study, not a randomized double-blind trial, received one

dose of HAVRIX. Adults received the dose that we now have a license for. The children received an experimental dose of 720 ELISA units; that is, twice the currently licensed children's dose.

All participants received only one dose of HAVRIX and adverse effects were solicited via diary cards. These number -- these results have been updated. Actually over 5,000 people now have received a single dose of HAVRIX. The vast majority of them were under the age of 20 but some adults received the 1440. Again, the majority of them were Alaska natives.

So this is what happened. And again, these are overall state statistics, not one town, one village. The time standard here is that basically Brian went into 30 villages and vaccinated people and he called vaccination day, day zero. So everything is referenced to the vaccination day on this graph.

So here one can see the epidemic building up and then the vaccination days came in here. And actually, the vast majority of these vaccination days occurred in a two month period.

This is what happened to the cases of

hepatitis A overall in the state and in the hepatitis A vaccinees. By eight weeks all cases were gone in the vaccinees and overall in the state there was a marked diminution.

Now, of course, epidemics go away by definition, so one doesn't know if it would have gone away. But it was interesting to note -- and I didn't bring the slide. In one village where the coverage was poorer, only about half of the susceptibles were vaccinated, the epidemic really continued in that village. And that was pretty powerful evidence.

In any event, this is what happened to the people who received hepatitis A vaccine in this project. There were some cases of hepatitis A in the vaccinees, not surprisingly, but I think that this is entirely consistent with the incubation period for the virus.

So that the vast majority of the cases occurred in week two or earlier after vaccination, but some cases occurred out as far as week three, four or five. No cases beyond this.

So, the conclusion was that the vaccine was well tolerated. I neglected to mention that in the

Thai trial there were no serious adverse events in 109,000 doses of vaccine.

In villages where more than 70 percent of the estimated susceptibles were immunized there was a dramatic drop in symptomatic cases of hepatitis A within eight weeks of vaccination.

I thought it might be helpful to you in the few minutes remaining to me to take a look at the indications in the prescribing information. So HAVRIX is indicated for active immunization against disease caused by hepatitis A and the following specific groups may be at increased risk: travelers -- and it lists the specific area. However the agency us to add a caveat here that travelers should consult CDC directories prior to travel. Military personnel is an indication in the label with no qualifications; people living in or relocating to areas of higher endemicity; certain ethnic and geographic populations that experience cyclic hepatitis A epidemics, such as Native Americans, persons engaging in high risk sexual activity, residents of a community experiencing an outbreak of hepatitis A -- and we were very gratified to receive that.

And then it goes on to say that although the epidemiology of hepatitis A does not permit identification of other specific populations at high risk, outbreaks of hepatitis A or exposure to hepatitis A have been described in a variety of populations in which HAVRIX may be useful, including certain institutional workers, such as caretakers of the developmentally disabled, employees of day care centers, laboratory workers who handle live hepatitis A virus, handlers of primates and animals.

And for those desiring both immediate and long-term protection, HAVRIX may be administered concomitantly with immune globulin. The only contraindication is in people with known hypersensitivity to any of the components of the vaccines.

As far as the food handlers, that's specifically not in the label. However, I did attend the last day's ACIP meeting which was several weeks ago and as Dr. Stevens said, there was a very weak statement about food handlers but it's also apparent that state epidemiologists are well represented on the ACIP and when there is an

outbreak attributed to a food handler, it's a huge problem for them. And I think the CDC will be strengthening the statement on food handlers.

So, finally, this is Walter Reed in Cuba after the Spanish-American War. This is to remind me to thank our collaborators at Walter Reed.

Thank you very much.

I'll be happy to take any questions.

DR. ASCHER: I'm confused. I made a comment about the licensing for children and you say there is a dose that's licensed for children?

DR. KRAUSE: Yes. The vaccine is licensed for children aged 2 through 18. It's a two-dose primary series given one month apart and a booster dose six to 12 months later.

DR. ASCHER: Why was that then not in your recommended group on your last two slides if that is very clearly part of the big problem?

DR. KRAUSE: Well, children can be travelers, and --

DR. STEVENS: Day care centers.

DR. ASCHER: No. It didn't say day care centers. It said employees.

DR. KRAUSE: No. It said employees of day

care centers.

DR. ASCHER: It said employees. That's a surprise.

DR. KRAUSE: The reason that it's not in there is that it's kind of -- more of a policy issue than a safety or an immunogenicity issue. So, as the label reads right now, if children are in one of those risk groups, they would be considered for vaccination.

DR. ASCHER: Children two to 18 years of age?

DR. KRAUSE: Correct.

COL. BANCROFT: In your last discussion of the community study, I'm not sure, what dosage did you use? Was that the 720 or --

DR. KRAUSE: For the adults 20 and older it was 1440. For those less than 20 it was an investigational dose of 720, half the 1440 dose.

DR. STEVENS: I just wanted to ask a question about the two doses of children. What's the comparison on the immune response to the two dose regimen versus the double dose the 7 --

DR. KRAUSE: You mean what's the zero -- the 360.01 versus 720 in children?

DR. STEVENS: Versus 720, one dose.

DR. KRAUSE: Right. We're doing those studies and we'll be submitting an amendment to the application this year, so it will be consistent. Children will be the same as adults.

DR. WOLFE: David, while you're there, could you answer my question posed before? What is this vaccine going to cost the military?

DR. KRAUSE: Well, ordinarily I'd dodge that question by saying ask the marketing guys, but they chose not to come with me so I can't really foist that upon them.

DR. WOLFE: Well, I can't believe that you don't know what they're going to charge.

DR. KRAUSE: Well, the dose that will be charged to distributors is $43 per dose and that's --

DR. WOLFE: That's for the civilian market?

DR. KRAUSE: That's in the Wall Street Journal today.

DR. WOLFE: Yes.

DR. KRAUSE: However, I honestly don't know the answer to your question about military use. I honestly don't know. I'm not trying to dodge it.

DR. WOLFE: I've been dodged for two years on this and I was hoping when the damn thing was licensed -- well, I guess they would be willing to commit to a cost so that if we're supposed to discuss this today and come out with recommendation we will have a tool to work here. There may be a reason why the marketing people didn't come.

MR. FLETCHER: File with the federal cost schedule is $32-something.

COL. BANCROFT: $32?

MR. FLETCHER: I think it was $32.75 but it is $32.

DR. WOLFE: Okay. Well, that's very helpful information. Thank you.

DR. POLAND: Per dose? Formula and inactivated?

DR. KRAUSE: Yes. The strain is HM-175 formula and inactivated, cultured in MRC-5, -- cells.

DR. POLAND: What other components are in the vaccine besides --

DR. KRAUSE: Aluminum hydroxide and 2-phenoxyethanol.

DR. POLAND: And what?

DR. KRAUSE: 2-phenoxyethanol is the preservative.

DR. STEVENS: I have a question about the dose issue as well. Since I think one of the previous speakers raised the issue about many people in the military being just short-term duty, is there a consideration for these vaccines to be given only in single dose?

COL. BANCROFT: We'd use as flew doses as necessary to protect the force.

DR. STEVENS: Aha. Is that a yes?

DR. KRAUSE: I guess what you can say is how long would a single dose protect?

COL. BANCROFT: I don't think with the vaccine -- the vaccine can be used differently than immune globulin. Immune globulin you give immediately before departure. The vaccine, since it gives prolonged protection, doesn't have the urgency of delivery. And so if you have to use two doses, three doses or more, there may be time to do it that you don't have with immune globulin.

DR. STEVENS: No. I meant just from the cost part of it.

DR. KULLER: I don't think you can do a

single dose, to be honest, if you've got an FDA approved and licensed vaccine for two doses, you have the cost. I mean, that's part of the discussion probably tomorrow. But I think the last thing in the world you want to do is suddenly decide you're going to do a different recommendation than the FDA has unless there was really an emergency where suddenly you can only give one dose because you're getting a lot of people out of the country and there's a real mess. But otherwise, you'd have a real problem.

LT. COL. KELLEY: I just wanted to make sure I understood one thing correctly. Is there a problem in the timing between the first and second dose?

THE REPORTER: Microphone, please.

LT. COL. KELLEY: I'm just curious if one dose for people entering the alert forces and then deferring the second dose until they actually deployed, realizing that most of them probably never deployed, would that be something that's an acceptable understanding in your scheme of things?

DR. KRAUSE: Well, what the label says is that travelers should wait 15 days following the

primary course, so that means the primary course for adults is one dose. So presumably travelers are protected 15 days after a primary dose.

Now, should you give a booster dose six to 12 months later, the purpose of which is to ensure long-term protection? Then that's kind of a policy issue.

The question that Dr. Stevens poses, if you give one dose, how long can one expect to be protected. And I don't know because we've never given one dose and not boosted at least a year later, so I can't answer the question for you.

LT. COL. KELLEY: I was just trying to get at whether it would be an acceptable policy to give one dose when people enter, say, the 82nd Airborne, and then for the small percent who actually do deploy at some point three, four -- two, three, four years down the line, give the booster then, so that for the bulk who don't actually end up deploying to endemic regions you save the second dose.

DR. KRAUSE: Well, that's kind of a policy issue. Again, I can't really answer that. And I can't tell you what happens if you give a dose and wait three years.

DR. ASCHER: The ones that cycle out just fall off of the system.

DR. KULLER: You'd give them one dose and then make sure they leave after a year.

(Laughter.)

DR. ASCHER: Lew, he said at any point in time it would not require a one-year limit. He said when they get deployed, two, three years later.

DR. KULLER: But that's not what the FDA --

COL. BANCROFT: There's no data on that.

DR. KULLER: There's no data on that.

DR. ASCHER: I know. That's what he proposed.

LT. COL. PARKINSON: The statement that you made that -- I just want to clarify the study where he said going out four years that you have 100 percent seropositivity. That study was based on a zero-one and six month schedule; correct?

DR. KRAUSE: Correct.

LT. COL. PARKINSON: What is that figure for what the FDA is licensing it for?

DR. KRAUSE: We don't have studies that are four years old. So what I can tell you --

LT. COL. PARKINSON: Wouldn't that be the schedule that the FDA is licensing it for, for the two dose?

DR. KRAUSE: Right. If one gives 720 zero-one-six, you get a geometric mean titer of about 4,000. The 1440 zero-six, you get virtually exactly the same titer. But there's no reason to think that the antibody kinetics would be different. But again, there are no data. The vaccine is not old enough.

DR. WOLFE: How about in Europe? Don't you have a couple of years experience with 1440? Didn't you get that licensed in Europe for a couple of years now?

DR. KRAUSE: Well, the vaccine that's licensed, Marty, is mostly the 720. There's a few countries.

DR. WOLFE: A couple of countries are using 1440?

DR. KRAUSE: A couple countries; Sweden, Switzerland, Belgium. But there's no long-term experience with the 1440. But I don't think there's any reason to think that it's any different.

DR. BROOME: Do you know -- you said that

there was no interference with the titers to the Hep-A when you looked at the co-administration. Did you look at the titers to the other antigens?

DR. KRAUSE: We've looked at the titers to some of the other antigens the other way, and that includes typhoid, polio, hepatitis B. It's four of five of them. I actually have a slide or a handout that I can show you after the meeting if you'd like. But basically, it approximates historical controls and I didn't -- we don't have data on geometric mean antibody titers, only on seroconversion rates.

DR. GWALTNEY: The issue of the FDA and how it relates to military medicine has come up in this group before and I don't know the answer. Maybe it's clear, but I'm confused about it.

If only the practices that are approved by the FDA can be used under any and all circumstances, and that's one thing. If the FDA has some flexibility in terms of military needs, in terms of use of drugs, then that raises a different issue. And it seems to me in the licensing of these products which have a military use, that should be part of the original deliberations by the FDA.

DR. KULLER: I think there's a different

questions that I'm hearing. Here, you're talking about an issue related to cost which is very different than an issue related to accessibility or logistics. Here the only reason that you wouldn't give the two doses is that it would save the military money. And it seems to me that that's very shaky grounds for any issue like that, as opposed to an issue related to logistics, which I would agree completely. But in here we're talking about a cost issue and I would be very nervous about making a recommendation on the basis of cost, especially when we're talking about costs which are relatively low in relationship to the higher Defense budget or other things, to save money from one to two doses. I think it's a very different issue.

DR. GWALTNEY: Well, I think some of us aren't really talking about cost. We saw the first vaccine was very effective after one dose and we also heard earlier that most cases of hepatitis A occur in troops after they've been in an area for some time. I wasn't sure whether that was because the immune globulin effect wore off or because by that time they were fraternizing with people in the area and then more exposed.

So you certainly could for scientific reasons alone say a strategy of one vaccination at the time of deployment would probably give you very good protection if those assumptions are correct.

DR. ASCHER: Including the delay of skipping to 12?

DR. GWALTNEY: Yes.

DR. KULLER: On more, and then I think we're going to have to go on.

DR. BROOME: I'm going to make two comments. One is we've had some very interesting discussions with the FDA about consistency of recommendations between the package inserts and the CDC-ACIP recommendations. And we have maintained that whereas whenever possible these should be very consistent, there are situations in which we are addressing the public health needs of vaccine usage and the package insert represents sort of negotiation between the FDA and the companies as to what they are willing to have in the package insert, which usually has different motivations than a public health and a military rationale.

DR. ASCHER: And we all know it's the allowable claims of the package insert that are

regulated. Once something is approved, off-label use and certain other uses, FDA does not really regulate that.

DR. BROOME: Well, it's not a trivial area. But I guess what I'd say in terms of military use is I think there's a rationale to be made for not being absolutely bound by or constrained by the FDA. I think whenever you can get data to support different uses or approaches, that that's far and away preferable in terms of being able to justify, for example, whether or not if you gave a booster three years out, you might do perfectly well. And that would be easy to test.

One other thing. I don't know if we're going to -- are we going to take up the cost effectiveness analysis?

DR. ASCHER: Absolutely.

DR. KULLER: Well, that's going to be the intent by the group later. That's later for the making of recommendations. Hopefully, this evening.

DR. BROOME: This evening? Okay.

DR. KULLER: Unfortunately, I think we're going to have to go on. This is going to continue tomorrow when we make the recommendations to the

Board, so hopefully there'll be some more discussion among the Board members and hopefully we can continue discussion tomorrow. But we have one more session and I think it's important that we do today, and that's our telemedicine briefing with Dr. -- Lieutenant Colonel Faye. And then we'll get back to hepatitis tonight after dinner -- maybe during dinner. We'll find out who has vaccine during dinner.

DR. WOLFE: Well, I may ask a question, Lewis, of the presenters? Does anybody here have a copy of the draft ACIP recommendations that we can use in our discussions this evening?

DR. KULLER: I think that would be very useful.

DR. BROOME: Also, just a point of information.

COL. BANCROFT: You have my handout and we can talk about it over dinner.

DR. BROOME: We have the assumption of the cost of IG, but that's the current military contract. And I assume when that's up the change in screening requirements and inactivation is going to mean it's going to cost more. And I think that's a

factor. And it would be nice to know if anybody has any ballpark estimate of what that cost would be.

DR. KULLER: Okay. Let's go on, now.

MR. EDWARDS: In the interest of time, I'll go ahead and get started telling you what -- describing these two handouts.

First, I'm Jess Edwards. I'm not Lieutenant Colonel Neal Faye. People make that mistake all the time, much to Neal's chagrin.

I would like to echo Colonel Bancroft's welcome on behalf of -- or greetings on behalf of Brigadier General Zajtchuk. Brigadier General Zajtchuk wears two hats. He's the Commander of the Medical Research and Material Command and he's also been asked by Dr. Joseph to serve as Chief Operating Officer of the DOD Telemedicine Testbed. And he serves in that role in support of Lieutenant General LaNoue, who serves as the Executive Lead Agent for the DOD Telemedicine Testbed.

Your bus comes to get you at 6:00 o'clock, so the good news is I'm going to be done by 6:00 o'clock. For those of you who just are not going to be satisfied with a 30 minute overview of telemedicine and the state of telemedicine in the

Department of Defense, I would encourage you to attend a National Forum on telemedicine the 27th, 28th and 29th of March.

We've put together what I would state as being an excellent agenda and that's one of the two documents that got handed out. We didn't bring enough copies. I didn't bring my skis like Colonel Lietch, but if you weren't able to get one of the National Forum agendas, I have a couple in the back.

And as long as I'm talking about Colonel Lietch, I don't have any stories to tell you about the sex lives of our Congress, but I will tell you that on January 30th, Representative Newt Gingrich to the American Hospital Association, said, "I come here today to ask the American Hospital Association and all its members to profoundly rethink your stance and your assumptions to literally say erase the board."

I don't care what your positions were as of 9:00 this morning. Just drop all of them and rethink it. If we could cut three to five years out of the transition from R&D to treatment and if we could be networked to things like Internet so that every doctor in every hospital has equal access to equal

information, so that literally when you walk in you're entering the world body of knowledge.

And I'll tell you, people like the Department of Defense are doing it. They're trying to design systems where a soldier who's been shot and has a particular problem is by distance medicine being connected directly from a field hospital to finest specialists on the planet.

Now we can do that for our young men and women in uniform because we have a large system systematically thinking through it, but then we ought to transfer that to everyone else. And that's probably as good a summation at a strategic level as we can come up with of one of the key drivers behind the DOD Telemedicine Testbed.

Again, this is who I am. These are the points I'd like to talk to you about today to give you some idea of the underlying theory driving telemedicine; where military medicine has been; where we're at and where we're going.

Basically, as you all know, we're reacting to the right sizing of the military as a result of the change in the Cold War. At the same time, we're enabled to do things we haven't been able to do in

the past as a result of advancing technologies. And we're doing our share for the nation to enact Health Care Reform.

As a result, we have some re-engineering initiatives underway. One of the driving forces behind telemedicine is that health care, like all the other service industries, we've hit a productivity ceiling because you basically can't replace one to one contact. And as a result, costs rise.

So the overall macro implication f this is that we must try to exploit telemedicine to re-engineer health care delivery, try to be more efficient and in the process, the main thing that's going to happen is we're going to remove time and distance barriers and preferably participate on the preventive side of the health care equation so that we can obviate the need for health care whenever possible.

Now, one of the paradigms that people talk about a great deal is realtime imaging, so that if you have a remote provider anywhere in the world, they can contact another health care provider anywhere in the world instantly and be able to

interact with them to discuss a patient and to have all of the viable patient information integrated into a television conference -- tele-video conference, rather.

Now, this is only one of possibility. I think for those of you who have ever done E-mail and rely on E-mail heavily, I think we're going to see the equivalent of multi-media E-mail emerge in health care to where a store and forward concept will be used a great deal more over the next five years or so.

Now, one of the impacts is we're going to see our organization evolve from a traditional hierarchy and become what's often referred to as an Ad Hocracy to where the anytime, anywhere property of information is going to be exhibited. And basically, what most -- a lot of people who are used to being at senior management levels, like a lot of people, are going to consider this to be information chaos. But it's going to have very profound effects on how our organizations interact and conduct business in the future.

Now, one of the working constructs is if we define for a moment the word spoke to be anybody who

needs health care, be they patient or primary care provider or subspecialist wanting to interact with another subspecialist, and define a hub as anyone or anything that can provide that health care information, be it computer aided diagnoses, immediate access to medical libraries, access to their friends that they went to med school with or subspecialists, a grid base will emerge -- a grid base matrix, rather, will emerge. And what this will do is it's going to enable something that we've been referring to as a digital free market.

When you have this sort of a grid forming you have an exponential increase in the opportunities to access one another and because of this exponential increase in access, we're going to see a system that will support competition on the basis of quality and we're also going to see an opportunity for competition to exist on the basis of price, as well.

And if you'll look at the goals of Health Care Reform, increasing access, lowering costs, improving quality, you know, for quite a while when I first started thinking about this, I thought these were essentially mutually exclusive goals and that

you could probably get any two of them without the third. But if you will allow the simple macro economic model to show that where you have supply and demand intersect, and you've got an equilibrium point for health care.

But effectively when everyone can talk to anyone through the use of computer based information systems, you're going to basically shift the supply curve and without adding providers, just the ability to talk to one another is going to effective increase the digital supply. This should have an impact on driving down costs and, as a result, enable quality improvements as well.

So, where we're been. Since 1985, military medicine has been working on radiology imaging systems. Initial research led to the letting of a contract in 1991 to the Loral Corporation and Siemens in a joint venture to build MDIS, the Medical Diagnostic Imaging Support System. MDIS represents currently the state-of-the-art in PACS, Picture Archiving and Communication Systems. Essentially in-house radiology. And this is something that military medicine can be very proud of because had it not been for the efforts of

military medicine, PACS would not be as far along as it is.

Essentially, what we've done is we've connected all the modalities that are already digital and then we've added computed radiography which represents about 70 percent of all imaging. And we've put them into a central file server. This central file server is capable of storing 10,000 images, which equates to a typical academic medical center, one week of in-patients, plus all the out-patients for the next day and for the current day.

Any imaging on here can be accessed by any workstation in two seconds or less, depending on the load on the system at the time. Where we've implemented this at Madigan and at Brook, this has just been a tremendous saving grace for clinicians.

We additionally have an optical disc juke box, which is 25 square feet are able to archive up to a million images. Now, one of the future product improvements is that this work storage unit is going to be increased so that we can store at least 80,000 images and that those images can, instead of just being radiographic in nature, will also be telemedicine images as well. So the ophthalmology

images, the pathology images, the dermatology images, basically this system is going to serve as the legacy system for the long-term archive of telemedicine still imagery.

We have for the past year been participating in something referred to as Operation Prime Time, which is a purple exercise to where we have soldiers up in Croatia, in Zagreb and on the mountaintops of Macedonia and through some commercial off-the-shelf technologies have been able to project the clinical expertise of Walter Reed onto these very remote mountaintops in Macedonia.

For one of these patients to be evacuated it takes approximately 4-1/2 hours to scramble the Medivac aircraft and to do all the in-country clearances, come pick up the patient and take them back to more sophisticated clinical care.

We believe that we have one case where we can show that a life was saved as a result of this telemedicine experiment.

Another thing that we've done is something called Operation Desert Hammer at the National Training Center, where basically the Army Medical Department was the first branch of the service to

ever move any kind of imagery over organic SINCGARS radios, tactical radios. And basically what we did was we took the moulage cards that some of you may be familiar with, the MILES cards, and we then went to CCRC to get video or still images that reflect that type of injury. So when a MILES casualty was taken, we were able to find a suitable image and to transmit it to the rear to enable tele-consultation.

Largely as a result of these efforts, the Chief of Staff of the Army has directed the Army to make telemedicine programmatic. And in order to comply with that, we've built a six part schema that will help us achieve those ends.

Now, I didn't have a bunch of numbers and statistics to throw up for you today, so I thought I'd just get a slide where everything is too small for you to actually read. But let me summarize this by saying that out here is where the casualties typically get taken on the forward edge of the battlefield and that between this point and back to other sites, it's very analogous to an emergency medical technician in an ambulance going out to provide care.

Once they get to the digital field

hospital, this digital field hospital is able to connect further back to the rear to places like Walter Reed, Balboa Naval Medical Center, Wright Patterson -- or, excuse me -- Wilford Hall. But basically the idea is to create an integrated network using the organic communications capability provided by the signal community so that we can enable telemedicine.

Another aspect of this is the mobile medical memory vehicle, the M3V. We're developing three different prototypes of it to serve in different roles. In the interest of time, I won't go into all of those.

We also, as part of the schema, interact very closely with ARPA. They have a budget, a core budget of approximately $30 million a year that they're investing in medical devices and what we recognize is that some percentage of those are going to be successful and we need to be able to very rapidly leverage those successes back into the field Army and field -- actually, tri-services.

And then there's T-Med 6, which is integration in our bases and telecommunications.

Now, in parallel with the Chief of Staff's

directive, Dr. Joseph basically directed General LaNoue to form the DOD Telemedicine Testbed. And the basic structure is that General LaNoue reports back to a Board of Directors that's organized under the auspices of Dr. Joseph and Admiral Martin and he, on a day-to-day basis, has asked General Zajtchuk to be the Chief Operating Officer. And then in our group, the Medical Advance Technology Management Office under the leadership of Colonel Fred Goerginger basically provides the staff to try to facilitate the activities of the Testbed while simultaneously executing the Army's tactical share of tactical telemedicine.

Now, the idea is that all the really good ideas in telemedicine are going to occur down at the hospitals, so we don't see ourselves as a bureaucracy driving the telemedicine agenda. We would prefer to see ourselves as enablers and facilitators to go out and find out what the clinical needs are of providers and then serve as a facilitator or a consultant to enable the solutions to their problems, using emerging advanced technologies.

It's a very different approach from the

traditional requirements driven methodologies that have been used to build things like CHCS. There's some anxiety depending upon who you talk to about whether or not that's going to work. But many of the senior leadership view this as the only way to effectively implement something on the kinds of timelines that are necessary.

We also want to participate -- I mean, this is obviously a DOD effort, so the Air Force and Navy both have officers and enlisted folks assigned to the Medical Advanced Technology Management Office, and then they also have resources back in the services. We want to cooperate with academia and industry. This is a huge collaboration effort.

So where are we at currently? We're at 15 minutes and counting.

We have a major five-year effort underway in the Pacific, referred to as the AKAMAI Project. Two years have been fully funded to date and that's enabled the building of the infrastructure and the initial efforts to build the telemedicine validation initiative out there so that next year if we're invited back we can start to share with you our data and our results of how telemedicine is affecting

clinical care.

Another project that we have underway we refer to Project Seahawk. This is essentially the world's largest experiment at re-engineering radiology services between health care facilities, where Madigan Army Medical Center because of its role as one of the initial MDIS sites is serving as the host for McChord, Yakima, the American Lake VA. And the Navy has four medical treatment facilities in the northern part of Puget Sound that will all be sort of integrated and will first go into Bremerton and it will serve the purpose of any radiographic image taken anywhere in the Puget Sound can be shown on any workstation anywhere in the Puget Sound. We think this has tremendous potential.

Where are we going? Well, early R&D had us always moving the patient rather than the information. And what we're trying to do is break that paradigm and start to move information rather than patients or really rather than providers. We spend a lot of time in military medicine moving individual providers to remote sites to provide subspecialty care and we see this is one way to break that.

Telemedicine needs to focus on primarily the clinical needs. You know, establishing what those needs are and then validating that there are efficacious ways of meeting those clinical needs using telemedicine. We also need to take a look at technical issues.

One of our biggest constraints in telemedicine is going to be available bandwidth. In other words, the size of the communications pipes. And as a result, things like compression are going to become very important and we have to validate exactly what kind of care can be rendered using what quality of image.

Over the long-term, we're going to see organization changes brought about by telemedicine in terms of organizational behavior and also the community culture will change and evolve. And also, manpower distribution within the system is likely to be affected one way or another. Ideally, with the goal of meeting the Health Care Reform goals to improve access, reduce cost and improve quality. But things will change.

And then obviously a huge part of this is going to be economic analysis. We need to

determine, given scarce resources, how to maximize and leverage those resources to provide the best care to the most people.

We expect this to be an ongoing process where we're going to have all sorts of different phases occurring simultaneously. There will be immediate things that we're doing. There'll be intermediate objectives that we're planning for and long-term objectives.

One of the things that we're going to do is by the end of the year we're going to stand up one or two M3V prototypes. We think that had this vehicle been available for something like Rwanda, one of the roles it might have served would have been to -- had it been one of the initial medical assets on the ground to help facilitate rapid surveillance of the problem.

Now maybe Rwanda is not the best example because the problems were so gross, but it could serve as basically the eyes and ears of providers and medical staff planners in the rear to better stage and allocate resources into the area.

Another thing we're doing -- this is a slightly different kind of graph but I wanted to

show this to you to make the point that we're a rapid prototyping enterprise. We want to maintain pace with the evolving technology. To do that, one of our very first goals is to maintain a clinical focus. That's putting pressure on us to maintain that kind of a focus to meet those needs with whatever technology happens to be available. We're always short of time. We thing this may actually be one of our scarcest resources and then there are other resources, manpower and financial. But those are the constraints.

But the kinds of things that we're trying to do is to develop a digital field hospital that we can deploy into Zagreb. The concept of the operation is that we have an ideal model of what the ultimate digital field hospital would look like. But then what we have to do is translate into something that we refer to as the art of the doable. The general officer decisions are going to be made by the DOD Board of Directors on whether or not to go forward, then we're going to launch an acquisition cycle, while simultaneously doing distributed clinical rehearsals at our testbed sites.

Some of the radiology, for example, will be tested out at Tripler. Some of the other telemedicine consultation will be tested at Walter Reed. But the goal is from April to July get ourselves in a position to where we can do some mission rehearsals out at someplace like Camp Bullis or Fort Hood or somewhere to where we can begin to work out technical bugs and doctrinal issues. This is an iterative process. And from there we're going to take our lessons learned, launch another acquisition cycle. And then by August of '95 go into a comprehensive integration trial in Zagreb where we try to pull all these subsystems together.

Now, we're almost already in March and we're saying that we want to have significant activity completed and running by August of '95. This is a very different model from other systems development efforts.

Meanwhile, in order to support that digital field hospital, we need to continually improve the capability of Walter Reed to serve as the digital catcher's mitt. You can't be sending a bunch of digital information out of theater unless you've got someplace that can catch it, process it and

participate in health care delivery as a result.

We have a seven year initiative underway in our program objective memorandum and the basic concept of that is that we will use Army exercises to test doctrinal issues and that as ARPA successes emerge, that we will also test those in those advanced war fighting exercises.

Now, going into this we have some ideas based on our observations of other civilian academic medical centers that have been doing telemedicine. If you really take a look at what they've been doing and then you ask them, "This is a fine system, but can you tell us something about your utilization?" They have very low utilization, in general. And some of the reasons why we believe that to be true is that the telemedicine systems that are deployed in academic medicine today generally meet the needs of the tertiary care provider and not the needs of the remote provider.

And as a result, it's the remote provider that needs to initiate the phone call and they're not initiating it. So, we think that we've got to focus on the remote clinician's needs. We've go to do it in a way in which we provide sufficient

information. We've got to do it in a way in which the system is imbedded and routine.

Most of the telemedicine systems now currently require the tertiary care provider to suspend what they're doing and to go to a single solidary room somewhere in the medical center to do a tele-consultation. This destroys their productivity and so it's no fun for the subspecialist. So we believe we've got to do it in a way in which these things become scheduled and become routine. Some of the implication of that, it's got to be taken to the desktop.

We want to provide reality based training. There's been a lot of tele-euphoria and as a result I think that some people probably have unrealistic expectations about telemedicine, and as a result with the sobering eventually comes the let-down would be harder than what it should otherwise.

So we're trying to be very realistic about where we're at, what the limitations are, but still keep our eye on the potential. Attitudes are very important. There are tele-evangelicals out there that will weather all the systems development problems and keep a smile and keep trying. This is

new and we're trying to do it rapidly and, as a result mistakes, are made. But what we try to do is learn as quickly from those mistakes as possible and fix them.

Now, there are some other success factors out there that make military medicine an absolutely unique and an invaluable resource to the nation in terms of our ability to serve as a telemedicine testbed. Our reimbursement issues are relatively easy compared to a fee for service competitive environment.

Yes, we do have some friendly turf issues between the tri-services, but we are essentially a single entity with a core set of values, so it should be easier for us to do this.

Licensure issues are not as aggravated for us. Some states are currently enacting new and higher licensure requirements -- well, they say it's to maintain quality under the threat of telemedicine providing inadequate services. But cynics think that it may be just an artificial barrier to entry that's being thrown up in the name of anticompetitive activity. But that's something that we don't need to worry about as much.

One of the success factors, obviously, is defining what success is going to be. Which costs are we going to consider to be relevant? And we need to certainly assure for patient confidentiality and basic security to ensure that we maintain the integrity of our data.

Another major initiative underway is that down in the state of Georgia under the title of the Center for Total Access, we're going to be collaborating with the Medical College of Georgia, George Tech. And Eisenhower is going to take the lead on doing various demonstrations, the most exciting of which I think is cooperating with local cable company to take telemedicine into the home.

And in the future, that should enable us to discharge patients earlier for some in-house or in-hospital stays, reducing the length of stay. And also it may be a more adequate way of following up on some of the long-term chronic problems to keep patients out of the system.

Another major activity that we have underway is something that we refer to as the Medical Federated Lab. We have two primary thrust areas. One of them is in telecommunications.

This is our way -- there are major efforts within the signal community to rapidly improve the capacity of their tactical systems and this is our tool that will allow us to maintain pace with the signal community.

Also, we have another technical thrust area in the way of simulation and this simulation is going to take place on a couple of different frontiers. One of them is to allow us to be integrated with the Chief of Staff of the Army's efforts to use simulation to practice -- to basically do dress rehearsals for battle. And right now the medics are not part of that play, but this will enable us to be part of that.

And also, this simulation will allow us to take advantage of some virtual surgery applications that probably won't do surgery but, you know, I think one of its values may very well be that it will enable rehearsals of surgery. If you can take a significant amount of diagnostic imagery and compile it to where you can basically replicate virtually the body of the patient you're about to invade and then go through some computer simulation rehearsals, then you should be able to do better

when the actual surgery takes place.

This is Star Wars. This is telemedical Star Wars. But if you know anything about the history of flight simulators, the first flight simulator was a 55 gallon drum on springs. So, this is visionary but it's imminently doable over the long haul.

In order to support this Medical Federated Lab, on Monday we have an Opportunity Conference at Fort Detrick. So far we have over 80 folks interested from industry and academia coming, wanting to participate and bid on this. And then we also want to put in another fun plug on the National Forum on the 27th through 29th of March.

Again, we're very proud of the agenda that we've put together and I would encourage you to participate in that if you can. Telemedicine over the next five to 10 years is probably going to be or has the potential to be one of the most significant elements in the changing health care delivery system. I mean, it's going to be -- it's probably going to be right up there with managed care in terms of how much organizational change it's going to enable and allow us to undertake.

One of the things that we're pretty proud

of is that the Chief of Staff of the Army, General Sullivan, has basically said that the AMED is the branch of the Army that has the lead in preparing for this Force 21 initiatives and that's something we're excited about.

Now if you can't get to the National Forum but you still want to learn some more about the testbed and you have access to MOSAIC or NETSCAPE, you can surf the Internet. This is where you've got to guide your surfboard. And basically, this is a graphically enriched home page that we try to maintain so that people can call in and find out what we're doing.

One of our underlying goals is to be as open as we can and to share information as much as we can. And then, this is how you can get ahold of me. I am no longer able to keep up with phone calls and so I'm -- no one ever really sees me. I'm just sort of virtual Jess.

And then we've got the World-Wide Web Server, but I've already given you that address. So, I'm available for questions now or afterwards if you want to go catch your bus.

Yes, sir?

DR. POLAND: My compatriots tell me they're hungry. I'll be brief. But I have three comments.

One is your somewhat off-the-cuff comment about you couldn't keep up with the phone is a real comment. When information is anywhere, anytime and anyplace, how will anybody keep up with that?

MR. EDWARDS: Well, that's an excellent point. I mean, there is the potential for data daily and I think our systems will become more and more sophisticated.

If we could do virtual surgical reversals, we ought to be able to build intelligent information filters.

DR. POLAND: My other two comments, I'll say them together, then you can answer them.

One is as we have more and more sophisticated systems, the more primitive systems atrophy. What do you do when the system is down and you don't get to answer that it doesn't go down.

And the second is how do you eventually guarantee security, which comes -- the more security built in comes in at an extraordinarily high cost?

MR. EDWARDS: Those are valid issues and those are certainly rate limiting steps or rate

limiting issues. But if you take a look at how valuable data is today, how valuable communications systems are today, they've been built so that they have tremendous amounts of reliability and availability and most good planners have disaster plans so that they can recover and come back up as quickly as possible.

The MDIS system, as sort of an example, has been up as a system in excess of 99.6 percent of the time, which is far more reliable than the ability of a clinician to call a filing clerk to get a film retrieved. So, there's tradeoffs. There will be no perfect systems but they will continue to become more reliability.

DR. POLAND: And for security, what will you do for that?

MR. EDWARDS: Well, you know, we have the intelligence communities, the spooks who spend a tremendous amount of time worrying about security and are investing tremendous amounts of money into doing research on how to improve the security of information systems. Clearly if they're successful in those very high dollar value investments, then those solutions ought to be able to be exported into

what is relatively minor security issues for health care delivery.

We don't have the answer today. Let's meet back here in 20 years and you can tell me if you're still worried about security of the information system.

DR. POLAND: It's not a minor issue, I guess?

MR. EDWARDS: It's not minor issue. You're absolute right. Military medicine has basically been doing this for 18 months and so there's no end. It's a target rich environment. There's lots to do.

Yes?

LT. COL. PARKINSON: Just one comment I shouldn't probably be making, but what the heck. It's the end of the day.

The slides you have there which is barriers to the utilization of this technology, I think each one are very significant. And I guess I would disagree with maybe even the first one, "Meeting An Unmet Need."

There may be very, very little need and that we're projecting the need in an era when our

doctrine is basically to take seriously wounded people out of theater as quick as you can and to have the system to do that. I mean, the ability to project medical care forward depends on the resources at the other end in that tent as much as who's on the phone at Walter Reed.

And I think there's a lot of conceptual work that probably has not been done on --

MR. EDWARDS: You're absolutely right.

LT. COL. PARKINSON: -- on where this is at. And we're racing forward. I mean, we just had a debate here about whether a dose of hepatitis A vaccine is $30 to $40 and that makes a big difference as to whether or not we're going to protect people from diseases that we put them in the way of.

And I would hope that in this process of leveraging resources that we really make sure that there is an unmet need at the other end, as opposed to letting radiologists who already are at a distance from a patient are further away to read an x-ray which basically they've got a basic Army term in antibiotics and a chest tube, which is really the interventions we're talking about at that end.

If it doesn't change the outcome of what we do to the patient or the time at which we Air-Vac them out, what's the value added? I mean, I'm sure we're looking at that, I hope, but I just wanted to get it on the table.

MR. EDWARDS: I mean, this is at least an hour long conversation. Since we don't have that, I'd assure you that we think we are very carefully managing this as a risk management process. We have an R&D program that's meant to go seven years. The investment in this is approximately $10 million a year. So we think we've pared this down and have got a very tight control over how we go forward.

We have some very significant organizational imperatives, though, that pressure us to move as quickly as we can.

All right.

DR. KULLER: Thank you very much.

MR. EDWARDS: Thank you.

DR. KULLER: We'll continue a lot of these discussions tomorrow and also tonight.

7:00 o'clock we're going to meet at the Billeting Office where you checked in.

(Whereupon, the proceedings were adjourned

at 6:15 p.m., to be reconvened on Friday, February 24, 1995 at 7:30 a.m. in the same place.)